ORAL ARGUMENT NOT YET SCHEDULED
No. 15-1335

United States Court of Appeals for the District of Columbia Circuit

MASTERS PHARMACEUTICAL, INC.,

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

On Petition for Review of Final Order of the Drug Enforcement Administration

FINAL BRIEF OF PETITIONER

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June 28, 2016

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

I. Parties

a. The following parties appeared at a hearing before the Honorable Gail A. Randall, Administrative Law Judge for the Drug Enforcement Administration:

Government

Drug Enforcement Administration

Respondent

Masters Pharmaceutical, Inc.

b. The following parties currently appear before this Court:

Petitioner

Masters Pharmaceutical, Inc.

Respondent

Drug Enforcement Administration

c. Petitioner makes the following disclosures:

i. There are no parent companies or any publicly-held companies that have a ten percent (10%) or greater ownership interest (such as stock or partnership shares) in Masters Pharmaceutical, Inc.

ii. Petitioner, Masters Pharmaceutical, Inc., is a corporation organized and existing under the laws of the state of Ohio with its principal place of business located at 11930 Kemper Springs Drive, Cincinnati, Ohio 45240. Masters Pharmaceutical, Inc. is a national secondary distributor of pharmaceutical products, including both controlled substances and non-controlled substances.

II. Ruling Under Review

Masters Pharmaceutical, Inc. petitions this Court for review of the Final Order, styled "Masters Pharmaceutical, Inc.; Decision and Order," of the Acting Administrator of the Drug Enforcement Administration, which revoked the controlled substances registration issued to Masters Pharmaceutical, Inc. by the Drug Enforcement Administration. The Final Order was published on September 15, 2015, in the Federal Register, 80 Fed. Reg. 55,418.[1]

III. Related Cases

Undersigned counsel is not aware of any related cases.

[1] On motion by Petitioner, this Court entered an emergency stay pending review of the Final Order.

Dated: June 28, 2016

Respectfully submitted,

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

*Authorities upon which we chiefly rely are marked with asterisks.

Statutes

Other Authorities

Regulations

GLOSSARY

ALJ:	Administrative Law Judge
APA:	Administrative Procedure Act
ARCOS:	Automation of Reports and Consolidated Orders System
CSA:	Controlled Substances Act
CSL:	Controlled Substance Limit
DEA:	Drug Enforcement Administration
DI:	Diversion Investigator
F.O.:	Final Order of the DEA Acting Administrator
Masters:	Petitioner Masters Pharmaceutical, Inc.
MFR:	Memo for Records
MOA:	Memorandum of Agreement
OSC:	Order to Show Cause
R.D.:	Recommended Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge
SOMS:	Suspicious Order Monitoring System
UR:	Utilization Report

JURISDICTIONAL STATEMENT

Masters is a national secondary wholesale distributor of controlled substances and holds a registration from the Drug Enforcement Administration ("DEA") to engage in such activities. The Decision and Order ("Final Order") of the Acting Administrator ("Administrator") revoking Petitioner's registration is a final order, which is subject to review upon a petition filed with the U.S. Court of Appeals for the District of Columbia Circuit within 30 days of the decision's publication. 21 U.S.C. § 877. The Final Order at issue in this case was served on Masters on September 9, 2015, and was published in the Federal Register on September 15, 2015. 80 Fed. Reg. 55,418 [hereinafter "F.O."]. Petitioner filed a timely petition for review on September 21, 2015.[2]

STATEMENT OF THE ISSUES

On petition for review, Petitioner raises the following issues:

1) Whether the Final Order should be vacated as arbitrary, capricious, and unsupported by substantial evidence when the Administrator based his findings on evidence that the Administrative Law Judge ("ALJ") properly excluded from the record.

2) Whether the Final Order should be vacated as in violation of Masters' due process rights because it is based on claims DEA never raised at the hearing.

[2] On motion by Petitioner, this Court entered an emergency stay pending review of the Final Order.

3) Whether the Final Order should be vacated as arbitrary, capricious, and unsupported by substantial evidence because the Administrator improperly rejected the ALJ's determinations about the credibility of key witnesses.

4) Whether the Final Order should be vacated as contrary to law because DEA announced substantive new duties Masters allegedly violated in a prior unrelated adjudication and without formal notice-and-comment rulemaking.

5) Whether the Final Order is arbitrary, capricious, and contrary to law insofar as it is based on Masters' refusal to relieve DEA of its burden of proof and accept responsibility for alleged misconduct prior to the hearing.

6) Whether the Final Order is arbitrary, capricious, and contrary to Masters' contract rights set forth in the 2009 Memorandum of Agreement between Masters and DEA.

PERTINENT STATUTES AND REGULATIONS

Relevant provisions of statutes and regulations are reproduced in the attached Addendum.

STATEMENT OF THE CASE

A. The Controlled Substances Act and DEA's Regulatory Scheme

The Controlled Substances Act ("CSA") and its implementing regulations create a "closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the

CSA." *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). DEA is responsible for the implementation and enforcement of the CSA, and anyone who seeks to manufacture, distribute, or dispense controlled substances must obtain a registration. 21 U.S.C. § 822(a).

The Administrator must grant or renew a distributor's application for a registration, unless doing so would be "inconsistent with the public interest." *Id.* § 823(b), (e). To decide if a registration is in the public interest, the Administrator must evaluate specific factors, including whether the registrant has maintained "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." *Id.* § 823(b)(1), (e)(1). DEA's security rule states:

> All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in [21 C.F.R. §§ 1301.72-1301.76] as standards for the physical security controls and operating procedures necessary to prevent diversion.

21 C.F.R. § 1301.71(a). Thus, sections 1301.72-1301.76 provide the exclusive and specific requirements that distributors must meet to maintain "effective controls." Only one requirement, section 1301.74(a), refers to the distributor's customers: The distributor must make a "good faith inquiry" to verify that a customer has a valid DEA and state registration. Only one requirement, section 1301.74(b), refers

to orders received by distributors. To satisfy this requirement, distributors must operate a system to *detect* "suspicious orders" and *inform* DEA when such orders are discovered. *Id.* § 1301.74(b). "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

The Administrator may suspend or revoke a registration if he finds that a registrant has acted in a way that would render continued registration "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). The Administrator must first serve the registrant with an order to show cause ("OSC"), listing the allegations on which the proposed sanction is based, and provide the registrant with an opportunity for a hearing. 21 C.F.R. § 1301.37. An ALJ conducts the hearing, which is governed by the Administrative Procedure Act ("APA") and DEA's hearing regulations; the burden of proof rests on DEA. *Id.* §§ 1301.41, 1301.44(e), 1316.52. Only after DEA meets its *prima facie* burden does the burden shift to the registrant to show it should be entrusted with a registration. *See, e.g.*, *Medicine Shoppe—Jonesborough*, 73 Fed. Reg. 364, 387 (Jan. 2, 2008).

The ALJ forwards its recommended findings of facts, conclusions of law, and decision to the Administrator. With consideration of, and deference to, the ALJ's factual findings and credibility determinations, the Administrator issues a final order either agreeing with (in full or in part) or rejecting the ALJ's

recommended decision. *See* 21 C.F.R. § 1316.67; *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005).

B. Masters' History as a DEA Registrant

Masters has been continuously registered with DEA since 2002 as a distributor of controlled substances in Schedules II through V, maintaining registration number RD0277409. Masters also maintains three DEA registrations (distributor, importer, and exporter) for its separate third-party logistics facility. Those registrations are not the subject of this case.

C. Masters' 2009 Settlement with DEA

On October 17, 2008, DEA served Masters with an OSC (the "2008 OSC"). Joint Appendix ("JA") 1401. The 2008 OSC alleged Masters had failed to maintain effective controls against diversion by selling hydrocodone to four "rogue Internet pharmacies" that Masters "knew, or should have known," were operating illegally. JA 1401-02. It also alleged that Masters had failed to report suspicious orders in 2007 and 2008. JA 1401-02. On April 1, 2009, Masters and DEA entered into an Administrative Memorandum of Agreement (the "2009 MOA") resolving the 2008 OSC. JA 898. The parties agreed to "settle and resolve . . . all outstanding administrative claims and/or issues with respect to the alleged failure of Masters to detect and report suspicious orders and the alleged failure of Masters

to maintain adequate controls against the diversion of controlled substances on or prior to April 1, 2009." JA 898. DEA agreed to:

> a. Release Masters . . . from any administrative claims within DEA's enforcement authority for the conduct alleged in [the 2008 OSC] and [the 2009 MOA]; and
>
> b. Refrain from filing any administrative claims against [Masters] within DEA's enforcement authority under 21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct.

JA 903.

The parties defined "Covered Conduct" to include the specific conduct alleged in the 2008 OSC, "the alleged failure of Masters to maintain adequate controls against the diversion of controlled substances, on or prior to April 1, 2009, at its distribution facility," *and* "the alleged failure of Masters to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before April 1, 2009." JA 899. DEA reserved the right "to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against [Masters] *for non-covered conduct*." JA 903 (emphasis added).

Masters agreed to pay DEA $500,000 and to implement a new compliance program "designed to detect and prevent diversion of controlled substances." JA 899-901. Under the new program, controlled substance orders that

> exceed established thresholds and meet other criteria as determined by Masters will be reviewed by a Masters employee trained to detect

> suspicious orders for the purposes of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is not suspicious and the controlled substances are not likely to be diverted . . . .

JA 899. Masters also agreed that it would analyze its recent sales of certain controlled substances and its existing customer due diligence files under its newly adopted compliance program and "take appropriate action" if required. JA 900.

D. DEA's August 2009 "Compliance Review"

Under the 2009 MOA, DEA played an important role in Masters' new compliance program. DEA agreed to perform a "Compliance Review" to determine whether Masters' new compliance program complied with DEA regulatory requirements, whether Masters had properly vetted its controlled substance customers, and whether Masters had detected and reported suspicious orders it may have received *after* April 1, 2009. JA 901-02. The parties agreed DEA's Compliance Review

> *will be deemed satisfactory* unless DEA determines that the facility being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances *after April 1, 2009*; or (iii) *failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances*.

JA 902 (emphasis added).

The Compliance Review would be deemed "not satisfactory" if DEA provided Masters with "written notice with specificity" stating that Masters had

failed to maintain effective controls against diversion, had failed to detect and report suspicious orders after April 1, 2009, or had failed to meaningfully investigate its new or existing customers' legitimate need to order controlled substances. JA 902. In the event DEA deemed the Compliance Review "not satisfactory," DEA agreed to "meet and confer with Masters within 48 hours" and to consider any further remedial measures Masters had taken to further improve its new compliance program. JA 902.

DEA conducted its Compliance Review of Masters' new compliance program on August 17 and 18, 2009. JA 557-60. It is undisputed that the Compliance Review was "deemed satisfactory" because DEA did not provide Masters with any written notice to the contrary. *See* JA 560, 902. Thus, Masters reasonably concluded that DEA had determined: (1) Masters' new compliance program was sufficiently robust to "maintain effective controls against diversion"; (2) it had detected and reported any suspicious orders it had received "after April 1, 2009"; and (3) it had "meaningfully investigate[d]" whether its customers had a legitimate need to purchase controlled substances.

In the OSC it issued four years later (the "2013 OSC"), JA 8, however, DEA alleged that Masters' 2009 compliance program did not effectively prevent diversion, that Masters had failed to detect and report suspicious orders that were placed prior to the Compliance Review, and that Masters had failed to conduct

meaningful due diligence on eight of its pharmacy customers, *each of which had been a long-term customer at the time of DEA's 2009 Compliance Review*. These same conclusions, all of which are directly contradictory to the conclusions DEA reached during the Compliance Review, form a significant basis for the Administrator's Final Order in this matter.

E. 2013 Order to Show Cause and DEA's Allegations

Like the 2008 OSC, the 2013 OSC alleged that Masters failed to maintain effective controls against diversion of controlled substances in violation of 21 U.S.C. § 823(b)(1) and (e)(1). JA 8-9. Specifically, DEA alleged that, between April 1, 2009, and March 31, 2011, the majority of Masters' sales of oxycodone went to customers located in Florida, and that those sales "well exceeded" its sales of oxycodone to customers in other states. JA 9. DEA also alleged that "the majority of Masters' largest purchasers of oxycodone products have been retail pharmacies in the State of Florida who Masters knew or should have known were" diverting the products for illegitimate use. JA 10. The 2013 OSC then identified the volume of oxycodone purchased by eight retail pharmacies, seven of which were located in Florida.[3] JA 10. However, apart from the amount of oxycodone

[3] The 2013 OSC addressed the volume of sales Masters made to two of the named pharmacies after January 1, 2009, and asserted that these purchases alone should have put Masters on notice that the pharmacies were engaged in diversion. JA 10. In those instances, the 2013 OSC expressly referenced sales made *prior* to the effective date of the 2009 MOA and its release, i.e., "Covered Conduct." JA 899.

purchased by the eight "named pharmacies" over various time periods, the 2013 OSC did not otherwise allege any facts that Masters knew or should have known that suggested the pharmacies were diverting the oxycodone they were purchasing.

Finally, the 2013 OSC alleged that Masters

> ignored and/or failed to implement its own due diligence and suspicious order monitoring policies, compromising the effectiveness of those policies . . . failed to conduct meaningful due diligence . . . fail[ed] to document red flags of diversion . . . [and] failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 C.F.R. § 1301.74(b).

JA 10. These conclusory statements were the only allegations in the 2013 OSC that did not relate to the *volume* of oxycodone sales Masters made either into the state of Florida or to the "named pharmacies."

The ALJ required both parties to file Prehearing Statements including a summary of the testimony of each witness. JA 13. The Order required DEA "to indicate clearly each and every act, omission or occurrence upon which it relies in seeking to revoke" Masters' registration; it also required Masters to "indicate clearly each and every matter as to which it intends to introduce evidence in opposition thereto." JA 14. The ALJ ordered that "summaries are to state what the testimony will be, rather than merely listing the areas to be covered" and that

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The 2013 OSC alleged that the purchases made by the remaining six named pharmacies *after April 1, 2009*, should have caused Masters to believe they were involved in diversion. JA 10. To this extent, the 2013 OSC alleged conduct that, if true, DEA was obligated to identify "with specificity" during its August 2009 Compliance Review. JA 902.

"testimony not disclosed in the prehearing statements or pursuant to subsequent filings is likely to be excluded at the hearing." JA 14.

The ALJ also ordered the parties to file written sworn declarations of certain key witnesses. JA 117; *see also* 21 C.F.R. § 1316.58. The written declarations constituted the direct examination of the witnesses. At the hearing, the declarations were admitted into evidence followed immediately by the opportunity for cross-examination.

Like the 2013 OSC and DEA's Prehearing Statement, the *volume* of Masters' oxycodone sales was the primary focus of the declarations of DEA's witnesses. At no time did DEA:

- Identify a single, specific order for controlled substances that it deemed suspicious due to its unusual size, substantial deviation from a normal pattern, or frequency;
- Allege that Masters had *failed to report* to DEA any order that Masters had deemed suspicious;
- Produce any evidence that *any* customer was actually engaged in the diversion of controlled substances or that any controlled substance sold by Masters was actually diverted to illegal use;

- Produce any evidence as to the reason why any order for controlled substances was held by Masters' Suspicious Order Monitoring System ("SOMS") for review by Masters' Compliance Department;
- Assert that Masters' written policies and procedures deemed suspicious *every* order for controlled substances held for review by Masters' SOMS;
- Establish the "normal" dispensing patterns of retail pharmacies;
- Allege that explanations provided to Masters by the named pharmacies for their ordering or dispensing patterns were false or suspicious;
- Put forth any evidence to prove that Masters' practice of deleting or editing orders for controlled substances resulted in diversion;
- Assert that Masters was required to establish the elements of equitable estoppel in order to enforce its contractual rights under the 2009 MOA;
- Make any allegation about conduct after March 31, 2011; or
- Assert that Masters' registration should be revoked solely because it refused to accept responsibility for its alleged wrongdoing.

Nonetheless, these claims and findings ultimately formed the basis for the Final Order revoking Masters' registration.

Aside from the evidence of the volume of Masters' sales of oxycodone, DEA's key witness, Diversion Investigator ("DI") James Rafalski, made allegations that were specific to each of the named pharmacies and the way in which Masters evaluated them under its written policies. Specifically:

- DI Rafalski reviewed Masters' due diligence files relating to each of the pharmacies, including information in those files that Masters gathered prior to April 1, 2009, and believed that Masters ignored "indicators of potential diversion that should have caused Masters to designate as suspicious (and report to DEA) many of the orders placed" by the pharmacy. *See, e.g.*, JA 1129, 1141-42, 1151, 1162, 1171-72, 1179, 1193-94, 1199-1200.
- DI Rafalski reviewed Utilization Reports ("URs") provided by each pharmacy that showed the number of dosage units of prescription drugs dispensed by the pharmacy during a specific time frame. JA 1113-14. Many of the URs were gathered by Masters prior to April 1, 2009. *E.g.*, JA 1130, 1142-43, 1152. After reciting the dosage units of oxycodone and other controlled substances dispensed, and the ratio of doses of controlled substances to other prescription drugs, DI Rafalski concluded that the information contained in the URs, had it been analyzed by Masters, would have alerted Masters that the pharmacies' purchases, specifically oxycodone 30mg, were "potentially suspicious" and "should have been investigated

prior to distribution." JA 1132-33, 1135-36, 1144-45, 1147, 1156, 1157-58, 1166, 1167, 1174-75, 1185-86, 1187-88.

- DI Rafalski also reviewed handwritten notes called "Memos for Records" ("MFRs") in Masters' due diligence files and alleged that Masters edited or deleted orders that exceeded the monthly thresholds established by SOMS, or would raise the threshold based on the content of the URs. JA 1175-78, 1188-90, 1204-05.
- Finally, DI Rafalski claimed that electronic "SOMS notes" created by Masters showed that Masters deleted or edited orders of oxycodone 30mg when the named pharmacies would reach their monthly threshold, potentially preventing the "issuance of a suspicious order." JA 1140-41, 1149-50, 1178.

F. DEA's Prehearing Motion in Limine

After Masters had submitted its written witness testimony, including evidence that Masters had continued to improve its anti-diversion program since 2011, DEA moved to preclude this evidence because it constituted "remedial measures." JA 148. DEA argued that Masters had to either accept responsibility for alleged wrongdoing before the hearing or be forever barred from doing so. JA 150-51. Because Masters "provided no notice to the Government or [the court] that it intend[ed] to accept responsibility for any misconduct," DEA argued that

Masters was precluded from introducing any evidence of remedial measures. JA 151. This left Masters in the untenable position of either accepting responsibility for conduct DEA had yet to prove (thereby absolving DEA of its burden of proof) or being barred from introducing evidence of improvements to its anti-diversion program. DEA withdrew its Motion only after Masters stipulated that it did not accept responsibility for alleged wrongdoing. JA 153.

G. Masters' Prehearing Motion in Limine

Masters filed a Motion in Limine to exclude evidence of "Covered Conduct" released in the 2009 MOA and all evidence that would deny Masters the benefit of the bargained-for Compliance Review. JA 125-28, 134-43. The ALJ granted in part Masters' Motion. The ALJ excluded numerous paragraphs of the written testimony of DI Rafalski, Wayne Corona, and DI Kyle Wright because the MOA precluded DEA from imposing administrative liability on Masters for "Covered Conduct." JA 159-63. The ALJ also precluded DEA from alleging Masters failed to conduct appropriate due diligence or report suspicious orders between April 1, 2009, and August 18, 2009 (the so-called "Period of Review"), because DEA's Compliance Review did not identify any such failures. JA 170. At no time did DEA argue, or the ALJ determine, that Masters was required to prove the elements of equitable estoppel in order to obtain the relief it sought.

As a result of the ruling, DEA could not establish liability based on Masters' conduct occurring before August 18, 2009. The ALJ limited the opinions critical of Masters offered by DI Rafalski and other DEA witnesses to information Masters gathered *after* the "Period of Review." JA 170. The ALJ also refused to consider as a basis for Masters' potential liability any information Masters gathered prior to August 2009. JA 170. Although such information could not easily be redacted from Masters' customer due diligence files, the ALJ refused to consider it. JA 163 n.3, 173 n.5. As a result, the question of whether information Masters gathered *before* August 18, 2009 should have caused it to be "suspicious" of certain pharmacy customers was not presented at the hearing.

The ALJ has the power to "[r]eceive, rule on, exclude, or limit evidence" presented at the hearing. *See* 21 C.F.R. § 1316.52(f). Yet, in his Final Order, the Administrator ignores the ALJ's evidentiary authority. The Final Order finds Masters liable for conduct that was properly excluded from the hearing, and which Masters never had the opportunity to rebut, all in violation of Masters' due process and contractual rights, and in violation of the DEA's duty to provide a "fair hearing." *Id.* § 1316.52.

H. Masters' Defenses to DEA's Allegations

Masters presented evidence at the hearing thoroughly rebutting DEA's allegations. In particular, Masters proved that DEA's "volume" evidence was

fatally flawed. *See* JA 335 n.22, 855-89, 908, 909, 1474-77, 1481-84. All that remained of DEA's case was DI Rafalski's criticisms of Masters' due diligence efforts and the way in which Masters administered its new policies and procedures after the August 2009 Compliance Review. Masters disproved each of those claims as well. For example, DI Rafalski conceded that, apart from the alleged failure to detect and report suspicious orders, he did not allege that Masters had violated any other DEA security requirement. JA 691-92. DI Rafalski also conceded that Masters reported to DEA more than 500 suspicious orders between April 1, 2009, and March 31, 2011. JA 700-03, 1065-96.[4] He admitted that, in addition to suspicious order reports, Masters routinely submitted "termination lists" to DEA identifying customers with which Masters had ceased doing business. JA 747-49,[5] 1260-1394. Finally, in his direct testimony, DI Rafalski failed to identify any specific order for controlled substances he deemed suspicious by virtue of its unusual size, pattern, or frequency (the relevant regulatory standard in 21 C.F.R. § 1301.74(b)). JA 1113-1207; *see also* JA 751-56.

Indeed, nowhere in the OSC, in any prehearing filings, or at the hearing did DEA identify a single order it deemed suspicious due to its unusual size, pattern, or

[4] DI Rafalski also conceded that *DEA's* suspicious order database was incomplete, and that it failed to capture at least some of Masters' suspicious order reports. *See, e.g.*, JA 708-15, 719-22, 724, 729-35, 740-42.

[5] DI Rafalski testified he was not aware that any other registrant provided this additional information to DEA. JA 697.

frequency as required under 21 C.F.R. § 1301.74(b). It instead rewrote the applicable regulations to create a new definition of "suspicious order." Rather than focus on the characteristics of the *order itself* as required by section 1301.74(b), the Administrator insists that Masters had a duty to declare orders suspicious based on the characteristics of the *customer placing the order*. JA 608-09. Although Masters has consistently argued that DEA has never properly promulgated a rule requiring it to do so, Masters nonetheless demonstrated that it conducted reasonable investigations of its customers, and took appropriate action when it obtained information that caused it concern. JA 1531-32, 1535-36, 1541-42, 1545-46, 1549-50, 1558-59, 1562-63, 1565-66.

Central to Masters' defense was the unrebutted testimony of Jennifer Seiple, Masters' Vice President of Compliance.[6] Ms. Seiple testified that Masters had investigated the dispensing patterns of the identified pharmacies, including both the volume of controlled substances they dispensed and the ratio of controlled to non-controlled substances, and concluded that each pharmacy had a reasonable explanation for the dispensing patterns shown on its URs. JA 1531-32, 1535-36, 1541-42, 1545-46, 1549-50, 1558-59, 1562-63, 1565-66.

[6] DEA chose not to cross-examine Ms. Seiple on any substantive topic during the hearing. The ALJ found her testimony credible. *See, e.g.*, JA 363, 403, 453-54, 505. Yet, as explained below, the Administrator rejected it entirely.

Ms. Seiple was present for DEA's Compliance Review and testified that DEA reviewed the due diligence files of four of the eight named pharmacies, but did not instruct Masters to stop selling controlled substances to those or any other pharmacy.[7] JA 1515-16. Although the other named pharmacies were then purchasing controlled substances from Masters and their due diligence files were available for review, DEA never sought to review them during the Compliance Review. JA 1516. DEA's representatives never advised Masters that any specific "red flag," any order for a specific quantity of controlled substances, or any specific dispensing pattern should cause Masters to conclude that a customer was engaged in diversion.[8] JA 1514-15. Instead, DEA confirmed that a pharmacy's location, its customer base, and other factors affect its legitimate need to order and dispense controlled substances. JA 1515. DEA instructed Masters to evaluate all the facts and circumstances surrounding a pharmacy, "ask questions," and "get the facts." JA 1514.

Ms. Seiple also testified about the reasons why Masters ultimately stopped selling controlled substances to each of the eight named pharmacies, and the fact

[7] DI Kyle Wright, who conducted the Compliance Review, admitted that he never instructed Masters to stop selling controlled substances to any customer. JA 651, 910-89.

[8] DI Wright also admitted that he did not provide Masters with *any* guidance about dispensing ratios or DEA's preferred method of evaluating customer URs. JA 656-57.

that Masters reported each to DEA by either identifying a suspicious order placed by the pharmacy or by naming the pharmacy on a "termination list." *See, e.g.*, JA 1522, 1532-33, 1537-38, 1543 (referencing termination list Exs. R62A-62NN). She also described the way in which Masters implemented the new compliance program it developed in the Summer of 2009. JA 1496-1512. She testified that Masters used customer URs for three main purposes:

> 1. To ensure that Masters is not selling the customer more than the customer was dispensing; 2. to determine whether the customer is dispensing a full-range of pharmaceutical products that would be expected of a legitimate pharmacy; and 3. to confirm that the customer's dispensing patterns are consistent with its stated business model.

JA 1506.

Ms. Seiple testified why Masters would "edit" or "delete" orders, and the interplay between market forces, Masters' business practices, and the Compliance Department's role in adjusting the amount of controlled substances customers could order. JA 1502-04. Ms. Seiple testified that, since April 1, 2009, Masters had identified and reported to DEA more than 2,100 suspicious orders placed by more than 900 separate DEA registrants. JA 1520; *see also* Resp't Exs. 61A-61E. Masters also refused to ship approximately 15 percent of the controlled substance orders it received after April 1, 2009. JA 1520. Masters provided DEA with "termination lists" of hundreds of registrants to which Masters refused to sell controlled substances. JA 1522; *see also* JA 1260-1394.

Ms. Seiple also described the changes Masters implemented to its policies and procedures based on recommendations DI Rafalski made during his visit to Masters' facility in February 2011. JA 1567-68. She described the other enhancements Masters made to its compliance program in the years prior to the hearing. JA 1571-72. Among other things, Masters voluntarily stopped selling all controlled substances to Florida retail pharmacies in July 2011, long before the 2013 OSC was issued. JA 639, 1524, 1604.

I. The ALJ's Decision

On June 19, 2014, the ALJ issued her 203-page Recommended Decision. Despite finding Masters had failed to report one suspicious order, the ALJ had "no difficulty" concluding that this minor violation did not warrant revocation of Masters' registration. JA 503, 509. The ALJ also found that, even though Masters did not obtain a new UR every time an order was held by SOMS, it had nonetheless implemented a system that effectively prevented diversion. JA 510.

The ALJ made numerous factual findings that the Administrator in his Final Order either ignored or rejected. For example, the ALJ found:

- DEA had "no proof that any of [Masters'] customers actually diverted controlled substances into illegitimate channels." JA 503.

- The record was "void of evidence showing that the pharmacies in question dispensed controlled substances based on illegitimate prescriptions." JA 503 n.130.
- After finding that DEA's evidence relating to Masters' average monthly shipments of oxycodone was "hopelessly unreliable," she held that there was "no credible evidence that the volume of controlled substances [Masters] shipped to Florida pharmacies or to the pharmacies in question was unacceptably large in comparison to other similarly situated pharmacies." JA 335 n.22, 504.
- Masters proved that the sales to the named pharmacies "were justified by the pharmacies' business models and customer bases." JA 504-05.
- Masters had presented "credible testimony" that, in accordance with its written policies, its compliance department had reviewed customer files, contacted customers, and verified the information provided prior to releasing orders held by SOMS. JA 505.
- Comparisons and analyses of customer URs were not required by any applicable statute or regulation. The manner in which Masters analyzed URs did not result in the failure to maintain effective controls against diversion. JA 510-11.

J. The Administrator's Final Order

On September 15, 2015, nearly 15 months after the ALJ issued her Recommended Decision, the Administrator issued his Final Order revoking Masters' registration. Like the ALJ, the Administrator rejected *all* of DEA's volume evidence. JA 321 n.8, 561 n.15. This Court could reasonably conclude that the Final Order is not supported by substantial evidence simply by recognizing that DEA's case was built primarily on "volume" evidence that both the ALJ and the Administrator completely rejected. Assuming this Court is willing to consider DEA's ancillary claims, for the reasons set forth below, it should conclude that the Final Order is not supported by either substantial evidence or the law.

SUMMARY OF THE ARGUMENT

This Court must vacate the Final Order because it is not supported by substantial record evidence, because DEA has no legal authority to enforce the rules Masters allegedly violated, and because DEA's actions in this case violate Masters' contractual rights under the 2009 MOA.

In the Final Order, the Administrator expressly relies upon evidence that the ALJ properly excluded from the hearing as a basis for Masters' liability. He finds Masters responsible based on arguments, allegations, and claims that DEA never made and that Masters never had the chance to rebut. He rejects testimony of Masters' witnesses the ALJ found credible, and credits the testimony of DEA

witnesses the ALJ found lacking.

The Administrator also holds that Masters violated purported regulatory duties it does not have. The Administrator imposes on Masters new security requirements in addition to the duties contained in DEA's regulations and bases his Final Order on Masters' alleged failure to follow those requirements. Because these substantive requirements amend existing regulations, but were never promulgated through notice-and-comment rulemaking, they are legally void, and the Final Order should be vacated. The Administrator also violates Masters' due process rights by holding that Masters' refusal to accept responsibility for conduct that was neither alleged nor proven was reason enough to revoke Masters' registration. Finally, he ignores Masters' contractual rights under the 2009 MOA.

For all these reasons, as explained in detail below, Masters urges this Court to vacate the Final Order and hold that Masters' continued registration is in the public interest.

STANDING

Masters has suffered an actual, concrete, particularized injury as a direct result of the Final Order revoking its DEA registration to handle controlled substances. Because vacatur of the Final Order will redress this harm, Masters has Article III standing. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-63 (1992).

ARGUMENT

I. Standard of Review

This Court may "hold unlawful" and "set aside" agency action that is arbitrary, capricious, an abuse of discretion, contrary to law or constitutional rights, in excess of statutory authority, or without observance of procedure required by law. 5 U.S.C. § 706(2)(A)-(D); *see Morall*, 412 F.3d at 177. DEA's fact finding must be supported by substantial evidence. 21 U.S.C. § 877. "Substantial evidence" affords "a substantial basis of fact from which the fact in issue can be reasonably inferred; it is more than a scintilla, and must do more than create a suspicion of the existence of the fact to be established." *Morall*, 412 F.3d at 176 (citations omitted). Moreover, agency action is not in accordance with law if it violates any law, including the agency's own regulations. *See FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003); *Environmentel, LLC v. FCC*, 661 F.3d 80, 84-85 (D.C. Cir. 2011).

II. The Administrator's Final Order Is Not Supported by Substantial Evidence and Violates Masters' Due Process Rights.

This Court will set aside any agency actions, findings, and conclusions that are unsupported by substantial evidence. 5 U.S.C. § 706(2)(E). The Administrator's factual conclusions are suspect if different from the conclusions of an ALJ "who has observed the witnesses and lived with the case." *Universal*

Camera Corp. v. Nat'l Labor Relations Bd., 340 U.S. 474, 496 (1951). An ALJ's decision is especially "significant" when, like here, it rests on "the importance of credibility in the particular case." *See id.* This Court has confirmed that the Administrator must carefully consider the recommended decisions of DEA's administrative law judges. *See Novelty, Inc. v. DEA*, 571 F.3d 1176, 1180-81 (D.C. Cir. 2009); *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005). In *Morall*, this Court vacated DEA's order revoking a registration because it failed to take into account the ALJ's findings and recommendation against revocation. *Morall*, 412 F.3d at 179-81. Noting that "credibility [was] central" to DEA's analysis, *id.* at 179, the Court stated that DEA's "departures from the [ALJ's] findings are vulnerable if they fail to reflect attentive consideration to the [ALJ's] decision." *Id.* at 177 (citation omitted).

Even where agency decisions *are* supported by substantial evidence, they will be set aside as violative of due process when they are based on issues not actually litigated during the administrative hearing. The APA requires an agency to provide the adverse party timely notice of "the matters of fact and law asserted." 5 U.S.C. § 554(b)(3); *see* 21 C.F.R. § 1301.37(c). This Court has held that an agency "may not make findings or order remedies on violations" not previously alleged by the agency or "litigated in the subsequent hearing." *Nat'l Labor Relations Bd. v. Blake Constr. Co.*, 663 F.2d 272, 279 (D.C. Cir. 1981). Even

when the record evidence could support a remedial action, this Court has stated that it will not enforce an agency order "in the absence of either a supporting allegation in the complaint or a meaningful opportunity to litigate the underlying issue in the hearing itself." *Id.* The APA's notice provision is intended to allow a party to "prepare an *informed* response." *Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975, 983 (D.C. Cir. 1974) (emphasis added).

Finally, due process requires that all adjudicatory proceedings, including those conducted by agencies, must be conducted by a "neutral and detached" adjudicator. *Morrissey v. Brewer*, 408 U.S. 471, 489 (1972); *see also Withrow v. Larkin*, 421 U.S. 35, 46 (1975) ("Concededly, a 'fair trial in a fair tribunal is a basic requirement of due process.' This applies to administrative agencies which adjudicate as well as to courts." (citations omitted)). Here, the Final Order falls far short of satisfying *any* of these bedrock principles.

A. The Final Order Relies Substantially on Excluded Evidence, Claims That Were Not Litigated, and Factual Findings That Have No Support in the Record.

In the 2013 OSC and at the hearing, DEA alleged that the named pharmacies' dispensing patterns and other information known to Masters should have caused Masters to conduct more thorough customer due diligence. *E.g.*, JA 9-10. The ALJ's prehearing ruling confined DEA's permissible evidence on these points to information Masters gathered *after* DEA's August 2009

Compliance Review. JA 159-63, 170. The ALJ refused to impose liability for information in Masters' due diligence files gathered before DEA's Compliance Review. JA 173 n.5.

The ALJ held that Masters was not legally required to analyze its customers' URs. JA 488. Nonetheless, she determined Masters had presented "ample evidence" to prove that each of the named pharmacies had "legitimate reasons for the high percentages of controlled substances" they dispensed. JA 497; *see* JA 488-97. The Administrator reached *opposite* conclusions based entirely on evidence excluded from the hearing. The Final Order asserts that information Masters gathered *before April 1, 2009*, about the named pharmacies' dispensing patterns created a "strong suspicion" that the pharmacies were engaged in illegal diversion—a suspicion that Masters' subsequent investigations failed to dispel.[9] JA 635. For example, the Final Order asserts that Tru-Valu's dispensing patterns, as demonstrated by a *December 2008* UR, "created not merely a suspicion, but a strong one at that, that Tru-Valu was diverting controlled substances." JA 617. Similarly, the Final Order alleges that "*[p]rior to April 1, 2009*, [Masters] had acquired information raising a strong suspicion as to the legitimacy of The Drug Shoppe's dispensing practices." JA 621 (emphasis added). And, "*[p]rior to April*

[9] As set forth in Section III, *infra*, even if these conclusions were true, neither the CSA nor DEA regulations obligate distributors to identify "red flags" of diversion, or require distributors to report to DEA orders that do not meet the statutory definition of a "suspicious order" found at 21 C.F.R. § 1301.74(b).

1, 2009, [Masters] had obtained substantial information creating a strong suspicion as to the legitimacy of Englewood Specialty Pharmacy's dispensing practices." JA 623 (emphasis added); *see also* JA 626 ("More than one year before April 1, 2009, [Masters] had acquired substantial information which created a suspicion as to the legitimacy of City View's dispensing practices."), 633 ("[A]s of April 1, 2009, [Masters] had obtained substantial information which raised a strong suspicion as to the legitimacy of Superior's dispensing practices."), 634 ("Prior to April 1, 2009, [Masters] had acquired substantial information that raised a strong suspicion as to the legitimacy of Morrison's dispensing practice.").

Not only did DEA *never make* these allegations at the hearing, they also constitute "Covered Conduct" for which Masters cannot be held liable. *See* JA 125-28, 134-43, 899. The Administrator's express reliance on excluded evidence, and his imposition of liability for "Covered Conduct" released in the 2009 MOA, are alone sufficient reasons to vacate the Final Order.

The Administrator's conclusions are not only legally indefensible, but they are not supported by the record. The record shows that Masters was *not suspicious* of the named pharmacies because each had undergone rigorous due diligence, including multiple site inspections, and each had provided reasonable explanations for their dispensing practices. Masters also passed DEA's August 2009 Compliance Review, which caused Masters to conclude that its due diligence was

"meaningful[]." JA 902. Had DEA believed otherwise, it was contractually obligated to provide Masters with "written notice with specificity" of that fact. JA 899, 902; *see* JA 125-28, 134-43.

As discussed in Section V below, the Administrator's analysis of the legal effect of the 2009 MOA is wrong. But, regardless of the legal effect of the Compliance Review, Masters was justified in concluding that its customers, including the named pharmacies, had demonstrated a legitimate need to purchase controlled substances prior to August 2009; the Administrator ignores this undisputed fact. By focusing (*sua sponte*) only on whether DEA was legally estopped from making allegations contrary to the results of the Compliance Review, JA 555, 564-65, the Administrator ignores the very real impact that the Compliance Review had on Masters' conduct following the review.

The Final Order is replete with other instances in which excluded evidence forms the basis for the decision to revoke Masters' registration. For example, the Administrator cites *excluded* paragraphs of DI Wright's declaration in criticizing Masters for failing to report allegedly suspicious orders placed by The Drug Shoppe and Englewood. *See* JA 621, 624. In dozens of other instances, the Administrator cites excluded portions of Masters' due diligence files as evidence supporting revocation. *See, e.g.*, JA 557-58, 624 (citing and quoting evidence excluded from Gov't Ex. 48A); JA 571 (citing and relying on excluded Gov't Ex.

16). Because the central conclusion of the Final Order—that Masters suspected the named pharmacies were engaged in the diversion of controlled substances and failed to take action—was based on excluded evidence, the Final Order cannot stand.

B. Because DEA Never Alleged Masters Failed to Report Orders That Were Suspicious Due to Their Unusual Size, Pattern, or Frequency, the Final Order's Contrary Conclusion Violates Masters' Due Process Rights.

DEA never identified in its OSC, prehearing statements, or written or oral testimony a single order for controlled substances placed by any Masters customer that DEA deemed suspicious due to its unusual size, its deviation from a usual pattern, or its unusual frequency. *See* 21 C.F.R. § 1301.74(b). Likewise, DEA never alleged that every order held for review by Masters' SOMS was *per se* suspicious and had to be reported unless Masters obtained and independently verified the reason for the order. For this reason, the ALJ's Recommended Decision neither addresses this argument nor identifies any such order.[10]

[10] The ALJ did conclude Masters failed to report a single suspicious order placed by Englewood Pharmacy on October 5, 2010. However, the ALJ did not deem the order suspicious because of its size, pattern, or frequency. Instead, she found that the order was "suspicious" because Masters observed suspicious behavior during an October 6 site inspection of Englewood. It is undisputed that Masters terminated Englewood's account on October 7, 2010, following that site inspection. JA 466. Both the ALJ and the Administrator erred in holding that 21 C.F.R. § 1301.74(b)'s definition of "suspicious orders" can be read to include orders of a ***normal*** size, pattern, or frequency placed by a pharmacy that displays "red flags" of potential diversion.

DEA instead advanced the theory that essentially all of the named pharmacies' orders were suspicious due to characteristics of the pharmacy itself, or inconsistencies in the information they provided to Masters. *E.g.*, JA 1134-36. DEA also claimed that Masters' alleged failure to adhere to its procedures and investigate inconsistencies rendered its compliance program ineffective. JA 1114-15, 1128-29. In response to these claims, Masters presented evidence that it had conducted reasonable due diligence on its customers, and that a member of its Compliance Committee reviewed each order held by SOMS and determined whether to further investigate or approve the order. JA 1500, 1530, 1534-35, 1540, 1545, 1549, 1558, 1561, 1564-65. Although Masters admitted that it did not obtain a new UR every time an order was held by SOMS, the ALJ held Masters' failure to strictly comply was not enough; DEA had to prove that diversion of controlled substances was the "direct and foreseeable consequence of" the failure to strictly adhere to the policy. JA 489-506, 509-10. At the hearing, DEA failed to link Masters' failure to strictly comply with its procedures to diversion of controlled substances.

Lacking this nexus, the Administrator asserted an entirely new argument based on a novel (and erroneous) interpretation of Masters' policies to find that Masters failed to report hundreds of suspicious orders. The Administrator determined:

> [Masters'] SOMS held those orders that were of unusual size, unusual pattern, or unusual frequency; *thus, where an order was held, that order met the specific criteria of a suspicious order as set forth in 21 CFR 1301.74(b).* Indeed, in the materials it provided to [DEA during the Compliance Review, Masters] specifically represented that "[t]he purpose of the [SOMS] is to ensure that potentially suspicious orders are flagged and reviewed by the compliance department."

JA 614 (emphasis added).

The Administrator devoted a significant portion of the Final Order to reviewing the orders placed by seven of the eight named pharmacies, speculating—often incorrectly—about the reasons why certain orders were held by Masters' SOMS, assuming—often incorrectly—what actions Masters took in response to receiving the orders, and then concluding that the orders were "suspicious" and should have been reported. DEA presented *none* of this analysis or argument at the hearing; therefore, Masters has never had the opportunity to challenge it.

The Administrator's conclusions are based upon an arbitrary interpretation of Section 6.2II of Masters' Comprehensive Policy and Procedure Manual. JA 1405-70. Although it is true that Masters' SOMS holds every order that is suspicious as defined in 21 C.F.R. § 1301.74(b), the SOMS also holds many orders that are *not* suspicious. *See, e.g.*, JA 1500. All orders held by SOMS can only be released by a member of Masters' Compliance Department. JA 1500. Masters' SOMS held for review *any* order for controlled substances that varied in *any*

respect from the volume, pattern, and frequency parameters established by the customer's ordering history. *See* JA 811-13, 1499-1500, 1395-1400.

As a result, SOMS held an order that exceeded the customer's Controlled Substance Limit ("CSL") by only one pill. JA 812-13. Similarly, SOMS held an order placed one day earlier or later than the customer's established ordering pattern. JA 813. SOMS likewise held any order that varied in any respect from the customer's established ordering frequency. JA 813. SOMS also held any order that included a controlled substance that Masters had never previously shipped to that customer. JA 1500. SOMS also held any order of any size placed by a customer that was on "compliance hold" for any reason. JA 765-67. Masters' Compliance Department routinely placed customers on compliance hold while it waited to receive URs or other information, JA 765-66, or while its Compliance Committee reviewed the account. JA 1500. None of these orders were suspicious, yet the Administrator assumed *all* of them were suspicious, and that Masters violated 21 C.F.R. § 1301.74(b) by failing to report them.

Contrary to the Administrator's interpretation, Masters' policy makes clear that held orders would *only* be deemed suspicious under certain circumstances:

> b. Disposition
>
> i. Orders held for review will be released and filled when:
>
> 1. The order is consistent with the customer's utilization report, AND

2. The customer's file, including survey responses and site visits is consistent with legitimate business practices.

ii. Orders held for review will NOT be filled when:
1. The order is NOT consistent with the customers' utilization report, OR
2. The customer's file, including survey responses and site visits, indicates that the customer may be engaged in inappropriate business practices, OR
3. The customer refuses to provide Masters with the information necessary to complete its evaluation.

JA 1436-37. Section 6.2IV states that "[a]ll orders that have been held for review [by SOMS] that Masters **does not fill** for the reasons set out in Section III(b)(ii), above, shall be considered 'Suspicious Orders' according to 21 CFR 1301.74(b) and reported to [DEA] . . . ." JA 1437. DEA presented *no evidence* that Masters failed to report any order that it was obligated to report under Sections 6.2III or IV.

The evidence confirmed that the *people* in Masters' Compliance Department, not the automated SOMS, determined whether held orders were "suspicious" based on all the information available to Masters at the time. JA 1499-1501, 1503. As the ALJ found, DEA's evidence that Masters had failed to investigate held orders was severely lacking:

> On redirect, DI Rafalski struggled to think of any instances where no additional due diligence was done after an order was held, and once again admitted that "in most cases the company did something." [Tr. 871-72]. Only after being heavily led by Government Counsel on redirect could DI Rafalski recall instances where he thought no additional due diligence was performed: situations in the due

> diligence files where orders seemed to be edited and deleted "based solely on controlled substance limits." [Tr. 871-72]. . . . [Resp't Exh. 103 at ¶¶ 47, 32; see also Resp't Exh. 103 at ¶¶ 155, 174, 201, 222, 241, 281, 300, 316].

JA 486.

The Administrator arbitrarily ignored this evidence and the ALJ's detailed findings. By incorrectly concluding that SOMS held *only* suspicious orders (which could only be released following a full investigation and verification), *see* JA 614, the Administrator not only misapprehends Masters' policy and ignores substantial credible evidence adduced at the hearing, but he also asserts an argument that DEA never made. The Final Order must be vacated because its conclusion that Masters failed to report hundreds of suspicious orders is based on the Administrator's new—and erroneous—interpretation of Masters' written policies, and his failure to consider substantial contrary record evidence.

C. Many of the Administrator's Factual Findings Are Not Supported by Substantial Evidence and Violate Masters' Due Process Rights.

The Administrator—acting more like an advocate than an impartial decision-maker—reached other arbitrary factual conclusions based on his "cold record" review of notes within Masters' due diligence files and DEA's Automation of Reports and Consolidated Orders System ("ARCOS") data. The Administrator conducted this review, which DEA never presented at the hearing, without the benefit of questioning the witnesses who wrote the notes. In many instances, the

Administrator's conclusions about what the notes meant, or the circumstances under which they were written, are wrong.[11]

For example, the Administrator concluded that orders placed by Tru-Valu on the last day of November 2009 "placed Tru-Valu over the 25,000 CSL, [but] the SOMS notes do not contain the name of the reviewer or an explanation for why the orders were shipped." JA 567. However, the orders Tru-Valu placed on the last day of November 2009 *did not* place it over the 25,000 CSL for the oxycodone family established in SOMS. The Administrator's error stems from his failure to recognize that Masters' SOMS considered oxycodone 80 mg, an extended release product not prone to abuse, to be in a separate "drug family" than other oxycodone products.[12] Had DEA advanced this faulty argument at the hearing, or cross-examined Ms. Seiple about it, the Administrator could not have reached this erroneous conclusion.

[11] The ALJ observed the peril inherent in attempting to interpret the meaning of the due diligence files: "DI Rafalski never asked the author of the SOMS notes or the MFRs notes to explain what the notes meant. Rather, he relied upon his own interpretation of these notes and information provided to him by former employees of the Respondent. [Tr. 783-84]." JA 455. During cross-examination, DI Rafalski admitted several of his interpretations were wrong. *See, e.g.*, JA 772, 777-78, 805-06.

[12] The Final Order acknowledges that Masters' SOMS placed controlled substances into separate "drug families" and "control groups," but the record is silent as to which drugs were placed in which families. JA 558.

The Administrator's analysis of Morrison's Pharmacy is another glaring example of his improper reliance on excluded evidence and the flaws in his personal evaluation of documents. Morrison's established its account with Masters in September 2007. JA 1560-61. On April 28, 2008, former DEA Diversion Program Manager and compliance consultant, Louis Fisher, inspected Morrison's on Masters' behalf. JA 91-92, 1561. The inspection confirmed that Morrison's had been in business since 2003, and that it serviced a nearby nursing home and an in-patient facility. JA 1561. As a result of its investigation, Masters was aware of the volume of oxycodone and other controlled substances dispensed by Morrison's and believed that it had a legitimate need for those products.

During the August 2009 Compliance Review, DEA's representatives reviewed Masters' due diligence file on Morrison's. DEA also inadvertently revealed that DEA was investigating the pharmacy. JA 1563. Masters immediately placed Morrison's on "non-controlled status" and, on August 27, reported Morrison's name to DEA. JA 1260-64, 1563. Masters' last sale of controlled substances to Morrison's occurred on August 17, the day before the Compliance Review. JA 1260-64.

The Administrator expressly relies on evidence that the ALJ excluded, makes incorrect assumptions about policies and procedures in place prior to August 2009, and concludes that Masters should have reported a controlled

substance order that was not, in fact, suspicious even under the Administrator's expansive definition. Based on his own review of Morrison's due diligence file, the Administrator concluded that "[p]rior to April 1, 2009, [Masters] had acquired substantial information that raised a strong suspicion as to the legitimacy of Morrison's dispensing practice." JA 634. Rejecting Ms. Seiple's unrebutted testimony, the Administrator concluded that Morrison's customer base and location "do not account for the volume of pain medications being dispensed and the percentage of oxycodone dispensed relative to other drugs."[13] JA 606. Finally, the Administrator claims that Masters should have reported as suspicious an order for controlled substances Morrison's placed on August 18, 2009.

The Administrator's conclusion that information Masters gathered about Morrison's prior to April 1, 2009, caused it to be suspicious is based on evidence the ALJ excluded from the hearing and is directly contradictory to the results of the Compliance Review. There was no testimony at the hearing to support the Administrator's conclusion that Morrison's location and clientele did not account for its dispensing practices. And, finally, Morrison's pharmacist placed the August 18 order—which Masters did not fill—"because her sales rep[resentative] told her to" and, therefore, Masters had no reason to deem it suspicious. JA 1252.

[13] DEA never presented this opinion at the hearing, and presented no evidence to suggest that Morrison's explanation for its dispensing patterns was not valid.

The Administrator's review of Masters' relationship with Morrison's exposes not only the biased and incorrect factual analysis that permeates the Final Order, but also the impossibly vague and extra-regulatory standard the Administrator seeks to impose on registrants. The Administrator's errors, and many more like them throughout the Final Order, are precisely why due process requires that litigants be made aware of, and be permitted to prepare an informed defense to, the claims asserted against them. DEA's conduct is especially egregious here where the Administrator effectively inserted himself as government counsel, conducted his own, arbitrary investigation of the evidence, shifted the burden of proof to Masters, and made findings directly contrary to the reasoned and well-supported findings of the ALJ. Masters was never given the opportunity to prepare any response—informed or otherwise—to the Administrator's interpretation of Masters' written policies, or the conclusions he drew from reviewing Masters' files and handwritten notes. For all these reasons, the Final Order violates Masters' right to due process. *See* 5 U.S.C. §§ 554(b)(3), 558(c); *Blake Constr. Co.*, 663 F.2d at 279; *Hess & Clark*, 495 F.2d at 983.

D. The Administrator Improperly Rejected the ALJ's Credibility Determinations.

The credibility of witnesses is of critical importance in this case. The ALJ consistently found DEA's evidence and witness testimony not credible. For example, the ALJ described the testimony of DEA's main witness, DI Rafalski, as

"equivocal," JA 487, a "misinterpret[ation]" of key facts, JA 371 n.41, 444-45 n.78, in need of "being heavily led" by DEA's counsel, JA 486, and as making an "'apples to oranges' comparison," JA 499. Similarly, the ALJ found the testimony and data presented by DI Wright to be "hopelessly unreliable" with "major discrepancies." JA 321 n.7, 335 n.22. The ALJ also described portions of the testimony of other key DEA witnesses to be "not credible," JA 417 n.68, 476, "contradicted," JA 477 n.100, and "less definitive," JA 487.

In stark contrast, the ALJ found the testimony of Masters' witnesses credible and persuasive. The ALJ detailed numerous instances where she found Ms. Seiple's testimony to be credible, JA 363, 398 n.53, 403, 453-54, 455, 476, 505, and "definitive," JA 487. She described the testimony of other Masters witnesses—including its statistics expert who debunked DEA's volume analysis—to be "credible." JA 320-21, 367 n.40, 474-75. The ALJ weighed the testimony she observed, and concluded that DEA had not met its burden. JA 510-11; *see Morall*, 412 F.3d at 166. The Administrator improperly substituted the ALJ's determinations with his own.

In particular, the Administrator disregarded the testimony of Ms. Seiple. The Final Order is replete with references to Ms. Seiple's alleged failure to address certain matters during her direct examination. *See, e.g.*, JA 555 n.5, 569-70, 602-03. Similarly, the Administrator repeatedly claimed that Ms. Seiple's entries in the

due diligence files are unexplained, appear to be inconsistent with other evidence, or appear to demonstrate that Masters failed to comply with its written policies and procedures. JA 555 n.5, 563 n.20, 565-606. Ms. Seiple's testimony addressed the allegations made by DEA in the 2013 OSC and witness testimony. DEA had the burden of proof; neither Masters nor Ms. Seiple was obligated to explain or rebut claims DEA never made. Had DEA believed Ms. Seiple's testimony was inconsistent with other evidence in the record, it had the opportunity to cross-examine her. It chose not to. *See* JA 841-45. It is wrong for the Administrator to conclude that Ms. Seiple's testimony is not credible because she failed to address claims that were never made or answer questions that were never asked.

The Administrator also rejected the ALJ's conclusion about the credibility of Ms. Seiple's testimony because, in the Administrator's view, her testimony was in conflict with other evidence in the record. JA 555 n.5. However, much of the evidence with which Ms. Seiple's testimony allegedly conflicted *was excluded by the ALJ*. *See* JA 570. The Administrator criticizes Masters for failing to develop suspicions about the legitimacy of the named pharmacies' dispensing practices based on evidence that Masters gathered prior to the Compliance Review. JA 570. Not only is any such failure on Masters' part not actionable, the Administrator ignores the substantial effect the successful Compliance Review had on Masters' opinions of the named pharmacies.

Finally, the Administrator repeatedly claimed that Ms. Seiple's testimony was "misleading." In support of this conclusion, he cited Ms. Seiple's testimony regarding each of the eight pharmacies:

> After [each pharmacy's] account was approved, Masters' SOMS system identified and held any order for controlled substances placed by [the pharmacy] that deviated from its typical volume, pattern or frequency. All such orders were released only after review by Masters' Compliance Department.

JA 1530, 1534-35, 1540, 1545, 1549, 1558, 1561, 1564-65. The Administrator asserted that Ms. Seiple's testimony was "misleading" because Masters' SOMS "was not even in operation until August 2009." JA 570; *accord* JA 578, 584, 629, 633. Presumably, this attack on Ms. Seiple's truthfulness is based on the fact that Masters shipped orders to these pharmacies prior to implementation of the SOMS in August 2009.

Any fair reading of the record, which includes undisputed testimony from both parties establishing that Masters' SOMS was developed during the summer of 2009 and placed in operation in August 2009, JA 1210, 1582, could only support the conclusion that Ms. Seiple's testimony referred to orders placed *after*—not before—SOMS was developed. Indeed, Ms. Seiple's testimony makes clear that her use of the term "SOMS" refers specifically to the proprietary, electronic system Masters developed in 2009. JA 1494, 1496. Thus, when Ms. Seiple testified that the SOMS identified and held any suspect orders placed by Masters' customers, it

is clear that she was not being misleading; she was referring only to orders that were actually processed by Masters' SOMS after August 2009. Had there been any doubt, DEA (or the ALJ) could have questioned Ms. Seiple about it.

In contrast to his treatment of Ms. Seiple's testimony, the Administrator ignored significant, material inconsistencies exposed during cross-examination of DEA's lead witness. *E.g.*, JA 321 n.8, 335 n.22, 363, 371 n.41, 403, 444 n.78, 454-55, 476-77, 487. For example, DI Rafalski repeatedly criticized Masters for failing to detect what he believed to be discrepancies in the due diligence information provided by the pharmacies. JA 417. On cross-examination, DI Rafalski was forced to admit his comparison was like "apples and oranges." JA 417. The ALJ also found that DI Rafalski made several clear errors when attempting to interpret Masters' due diligence files. JA 455.

The Administrator's attack on Ms. Seiple's credibility is reminiscent of the actions of the then-Deputy Administrator in *Morall v. DEA*—actions that this Court condemned as "arbitrary and capricious." 412 F.3d at 180. In *Morall*, the Deputy Administrator alleged that a doctor, or one of her family members, was abusing drugs, despite "relevant contradictory evidence, including evidence that led the ALJ to contrary findings of fact and credibility." *Id.* This Court held that the Deputy Administrator's insinuation—in disregard of actual evidence—was

"gratuitous and condemnable," ruling that the final order could not "withstand substantial evidence review." *Id.*

The courts' message is clear: DEA must consider all evidence that runs contrary to its decision. Here, among other things, the Administrator failed to consider that: (1) There was no evidence that any controlled substance Masters sold was illegally diverted; (2) in 2011, Masters voluntarily stopped selling all controlled substances to Florida pharmacies; (3) Masters substantially improved its anti-diversion program in response to DI Rafalski's criticisms; (4) after the Compliance Review, Masters' sales of controlled substances decreased substantially; and (5) none of DEA's allegations concerned conduct occurring after March 31, 2011. All of these undisputed facts run counter to the Administrator's findings about Masters.

The Administrator's arbitrary rejection of Ms. Seiple's testimony and his failure to consider undisputed evidence favoring Masters requires this Court to vacate the Final Order. *See, e.g.*, *Wedgewood Village Pharmacy v. DEA*, 509 F.3d 541, 549, 553 (D.C. Cir. 2007) (vacating DEA's final order revoking a registrant's license because the final order failed to consider an important part of the issue); *Morall*, 412 F.3d at 180, 184 (vacating DEA's final order revoking a registrant's license because the final order failed to consider contradictory evidence); *Humphreys v. DEA*, 96 F.3d 658, 666 (3d Cir. 1996) (vacating DEA's final order

that lacked any analysis of one of the registrant's defenses). An agency's decision is *not* supported by "substantial evidence" if it is not based on a "fair estimate of the worth of the testimony of witnesses." *See Universal Camera*, 340 U.S. at 490. If permitted to stand, the Administrator's arbitrary disregard for the ALJ's credibility determinations and undisputed evidence favorable to Masters renders meaningless the APA's hearing process.

III. The Final Order Should Be Vacated Because It Unlawfully Imposes New Duties on Distributors That Can Only Be Implemented by Notice-and-Comment Rulemaking.

In order to determine whether a registrant has maintained "effective controls" against diversion of controlled substances, and thus whether its continued registration is in the public interest, "the Administrator shall use the security requirements set forth in [21 C.F.R. §§ 1301.72-1301.76] as standards for the physical security controls and operating procedures necessary to prevent diversion." 21 C.F.R. § 1301.71(a). These specifically enumerated "physical security controls and operating procedures" do not require a distributor to perform due diligence on its customers; the only requirement is that distributors make a "good faith inquiry" to verify that a customer has a valid DEA and state registration. *Id.* § 1301.74(a). Distributors also have an obligation to identify and report to DEA "suspicious orders," which "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

Id. § 1301.74(b).[14] There is no obligation, however, to declare an order suspicious due to characteristics of the customer placing the order.

In the Final Order, the Administrator vastly expanded the duties imposed on distributors by part 1301. Specifically, he held that DEA's adjudication in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487, 36,498-502 (July 3, 2007), created a binding rule requiring registrants to conduct due diligence; a specific duty stemming from 21 C.F.R. § 1301.71(a)'s general duty to provide "effective controls" to prevent diversion. JA 612. The Administrator also concluded that Masters failed to report orders it should have deemed suspicious "because of the circumstances surrounding a customer's business or dispensing practices." JA 611. Within these purported general duties, the Administrator finds numerous specific requirements: (1) "[A] distributor must use the URs in evaluating whether a customer's dispensing ratio is suspicious" (JA 555); (2) "[e]ven if the Agency's regulations do not require a distributor to document the reason provided by a customer to justify a suspicious order, documenting that reason is still an essential part of maintaining effective controls . . ." (JA 563 n.21); (3) "a distributor must conduct a reasonable investigation 'to determine the nature of a potential customer's business before it' sells to the customer" (JA 612); (4) "the distributor must conduct 'additional investigation to determine whether [its customer is]

[14] The regulation does not require a distributor to refrain from shipping such orders.

filling legitimate prescriptions'" (JA 612); (5) "depending upon the circumstances, a distributor may need to perform site visits before it engages in any distribution of controlled substances" (JA 612); and (6) the "investigation must dispel all red flags indicative that a customer is engaged in diversion . . ." (JA 613).

Masters has consistently argued that the plain language of the regulation, as well as the APA's requirement that substantive agency rules be adopted only through formal notice-and-comment rulemaking procedures, prevent DEA from sanctioning Masters for failing to conduct more rigorous due diligence on its customers, or failing to deem an order suspicious based on characteristics other than the order's size, pattern, or frequency.

The Administrator rejected this argument by asserting that an agency is not required to announce "all rules it adopts only through notice and comment rulemaking." JA 611. This statement is, of course, true. But while an agency may under certain circumstances announce rules through adjudication, such power is not unshackled. An agency may *not* adopt "legislative" or "substantive" rules through adjudication. Such rules, which "grant rights, impose obligations, or produce other significant effects on private interests," *Batterton v. Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980), may *only* be adopted through formal notice-and-comment rulemaking. *Mendoza v. Perez*, 754 F.3d 1002, 1020-21 (D.C. Cir. 2014) (describing a legislative rule requiring notice-and-comment adoption as

"'one that does more than simply clarify or explain a regulatory term, or confirm a regulatory requirement, or maintain a consistent agency policy' . . . . A rule is legislative if it supplements a statute, adopts a new position inconsistent with existing regulations, or otherwise effects a substantive change in existing law or policy" (internal citations omitted)).

This Court has also restricted an agency's ability to bypass notice-and-comment rulemaking through adjudication when a new rule would conflict with or amend a preexisting rule *originally created* through rulemaking. *Ass'n of Flight Attendants-CWA v. Huerta*, 785 F.3d 710, 718 (D.C. Cir. 2015) ("It is true enough that 'if a second rule repudiates or is irreconcilable with a prior legislative rule, the second rule must be an amendment of the first; and, of course, an amendment to a legislative rule must itself be legislative.'" (internal citations omitted)); *Am. Fed'n of Gov't Emps. v. Fed. Labor Relations Auth.*, 777 F.2d 751, 759 (D.C. Cir. 1985) ("[A]n agency seeking to repeal or modify a legislative rule promulgated by means of notice and comment rulemaking is obligated to undertake similar procedures to accomplish such modification or repeal."); *see Marseilles Land & Water Co. v. Fed. Energy Regulatory Comm'n*, 345 F.3d 916, 920 (D.C. Cir. 2003) ("[A]n administrative agency may not slip by the notice and comment rule-making requirements needed to amend a rule by merely adopting a *de facto* amendment to its regulation through adjudication."). This Court has recognized that a contrary

interpretation of the APA would allow agencies to "effectively repeal legislative rules . . . by adjudication, without providing affected parties any opportunity to comment on the proposed changes, and without providing any significant explanation for their departure from their established views." *Am. Fed'n of Gov't Emps.*, 777 F.2d at 759.

The Supreme Court recently explored this interpretation of the APA in *Perez v. Mortgage Bankers Association*, 135 S. Ct. 1199 (2015). While the Court held that notice-and-comment requirements did not extend to revising agency "interpretations" of rules, it affirmed the APA's "mandate that agencies use *the same procedures* when they amend or repeal a rule as they used to issue the rule in the first instance." *Id.* at 1206 (emphasis added). The APA, and its interpretation by this Court and the Supreme Court, is clear: When an agency adopts new substantive rules, or amends or revokes a rule previously promulgated through legislative rulemaking, it must use notice-and-comment rulemaking. An agency's failure to do so renders unlawful any order or action based on this failure, and necessitates vacating that order. *Am. Fed. of Gov't Emps.*, 777 F.2d at 759.

This Court should vacate the Administrator's Final Order because it was based on Masters' alleged failure to comply with substantive duties that are in addition to, and effectively amend, DEA's existing security regulations and that

were arbitrarily and unlawfully adjudicated outside of the APA's rulemaking procedures. *See id.*

Even if this Court concludes that the additional due diligence requirements first announced in *Southwood* were merely interpretive rules, the inquiry would not end there. Although an agency's interpretation of its regulations is entitled to substantial deference, this Court must reject an interpretation that is "clearly contrary to the plain and sensible meaning of the regulation." *Huerta v. Ducote*, 792 F.3d 144, 153 (D.C. Cir. 2015) (internal citations omitted). The plain meaning of 21 C.F.R. 1301.71(a) requires DEA to use sections 1301.72 through 1301.76 to determine whether a distributor has maintained effective controls against diversion. Although those sections require a distributor to verify its customer's licensure, they do not require any additional due diligence. Moreover, because 21 C.F.R. § 1301.74(b) defines a "suspicious order" only by reference to characteristics of the order itself, it is unreasonable to interpret that definition to also include characteristics of the pharmacy placing the order. Because the plain language of the applicable regulation does not require distributors to conduct due diligence on their customers, DEA's contrary interpretation must necessarily be rejected.

Lastly, in *Southwood*, DEA revoked an *internet* pharmacy distributor's registration based, in part, on its failure to conduct due diligence of its pharmacy customers. 72 Fed. Reg. at 36,498-500. The decision provides little legal

precedence—it relies instead on DEA guidance documents concerning internet pharmacies—and its opinion turns on the specific facts presented, which are not analogous to the facts presented here.

IV. The Final Order Is Arbitrary, Capricious, and Not in Accordance with Law Insofar as It Is Based on Masters' Refusal to Accept Responsibility for Its Alleged Misconduct.

The Administrator held that Masters' failure to accept responsibility for its alleged misconduct is "reason alone to revoke its registration." JA 636. In other words, the Administrator held that the revocation of Masters' registration was warranted because Masters refused to admit it had violated the applicable regulation *before* the hearing and *before* DEA had established its *prima facie* case.[15]

The Administrator's standard is contrary to the APA and DEA regulations because it improperly places the burden of proof on Masters. *See* 5 U.S.C. § 556(d); 21 C.F.R. § 1301.44(e). It also places Masters, and all registrants, in the untenable position of either accepting responsibility—prior to a hearing on the merits and a determination of whether the government has met its burden—or being sanctioned for failing to do so. In a recent decision, the Acting Administrator stated a position contrary to his position here. The Administrator

[15] DEA's Motion to Preclude forced Masters to choose between accepting liability before the hearing or introducing relevant evidence of changes it made to its compliance program. *See* JA 148-52.

noted that the proposition that a respondent, "as a condition of being able to offer evidence of his remedial measures, is required to admit to the allegations before he even has the opportunity to challenge the Government's evidence," is *not* supported by agency precedent. *In re Hatem M. Ataya*, 81 Fed. Reg. 8221, 8224 (Feb. 18, 2016) ("[The] Agency has never held that a respondent must admit to his misconduct prior to even being able to test the Government's evidence at the hearing."). However, DEA argued, and the Administrator determined, the opposite here: Masters was required to accept responsibility and provide notice of the same prior to any hearing, prior to any determination whether the government met its *prima facie* case, and prior to the presentation of Masters' remedial case. As such, the Final Order is contrary to law and should be vacated. *See* 5 U.S.C. § 706(2)(A).

V. The Final Order Is Arbitrary and Capricious Because It Violates Masters' Rights Under the 2009 MOA.

A. DEA Is Bound by Its Agreement with Masters.

When the government "enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals," and "[r]ights against the United States arising out of a contract with it are protected by the Fifth Amendment." *Lynch v. United States*, 292 U.S. 571, 579 (1934); *see also United States v. Winstar Corp.*, 518 U.S. 839, 895 (1996). Further, "[b]oth as a matter of contract and as a principle of law, once the

Government accepts the work required under the contract, that acceptance is binding on the parties." *See Decker & Co. v. West*, 76 F.3d 1573, 1582 (Fed. Cir. 1996). In accordance with the 2009 MOA, DEA provided Masters with a complete release for "Covered Conduct." It also reviewed and deemed satisfactory Masters' Compliance Program. These actions are binding on the Agency.

The ALJ's exclusion of certain evidence DEA sought to present, and her ruling prohibiting DEA from sanctioning Masters for "Covered Conduct," were required to enforce Masters' rights under its contract with DEA. The Administrator's subsequent reliance on excluded evidence and "Covered Conduct" represents a gross violation of Masters' rights under that contract.

B. The Doctrines of Waiver and Equitable Estoppel Preclude the Administrator's Reliance on Claims Based on Conduct Subject to the MOA and MOA Compliance Review.

The Administrator asserts that Masters' rights under the MOA should be "evaluated by applying the principles of equitable estoppel." JA 564. In fact, the equitable doctrine of waiver is better suited to the facts of this case. But, even if the Administrator is correct, both estoppel and waiver prohibit the Administrator from making findings in violation of Masters' contractual rights.

1. The Government Waived Claims Against Masters.

Waiver is the "intentional relinquishment or abandonment of a known right." *United States v. Weathers*, 186 F.3d 948, 955 (D.C. Cir. 1999) (citations and

quotation omitted). When asserted against the government, waiver "will not be implied, but instead must be surrendered in unmistakable terms." *United States v. Phillip Morris Inc.*, 300 F. Supp. 2d 61, 69 (D.D.C. 2004) (quoting *United States v. Cherokee Nation of Okla.*, 480 U.S. 700, 707 (1987)).

DEA contractually waived in unmistakable terms its right to bring claims against Masters for certain conduct. *See Phillip Morris*, 300 F. Supp. 2d at 69. DEA entered into an MOA with Masters that: (1) released Masters from any failure to maintain effective controls or report suspicious orders prior to April 1, 2009; and (2) obligated DEA to provide Masters with "written notice with specificity" if DEA's August 2009 Compliance Review detected any deficiencies in Masters' new compliance program or its suspicious order reporting after April 2009. *See* JA 901-02. By entering into this contract, DEA unmistakably waived its right to sanction Masters for conduct that occurred before April 1, 2009, and agreed to provide notice of certain conduct occurring before the Compliance Review. The Administrator clearly erred in holding Masters liable for claims that DEA expressly waived.

2. Equitable Estoppel Bars DEA from Making Findings Contrary to the MOA.

The doctrine of equitable estoppel precludes claims against Masters for conduct DEA previously sanctioned. This Court has held that the "[t]he fundamental principle of equitable estoppel applies to government agencies, as

well as private parties." *ATC Petroleum, Inc. v. Sanders*, 860 F.2d 1104, 1111 (D.C. Cir. 1988) (citing *Inv'rs Research Corp. v. SEC*, 628 F.2d 168, 174 n.34 (D.C. Cir. 1980)). This Court and others have recognized the compelling policy reasons to hold the government to its contracts. *See Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 60-61 (1984) (applying estoppel against the government may be justified by the "interest of citizens in some minimum standard of decency, honor, and reliability in their dealings with their Government"); *Brandt v. Hickel*, 427 F.2d 53, 57 (9th Cir. 1970) ("To say to these appellants, 'The joke is on you. You shouldn't have trusted us,' is hardly worthy of our great government."); *Menges v. Dentler*, 33 Pa. 495, 500 (1859) ("Men naturally trust in their government, and ought to do so, and they ought not to suffer for it."); *see also Giglio v. United States*, 405 U.S. 150, 154-55 (1972).

Despite the strong public interest involved, the Administrator concludes that estoppel does not apply because Masters' reliance on DEA's silence following the Compliance Review was unreasonable, and because there was no evidence of "affirmative misconduct" on the part of the DEA investigators. *See* JA 564; *see also Heckler*, 467 U.S. at 60. Both of these conclusions are unsupported by the record. The Administrator claims Masters' reliance was unreasonable because "while the DI did not identify any specific deficiencies in [Masters'] policies and procedures, he advised [Masters'] employees that he perceived 'potentially

problematic trends' in its sales to several of the pharmacies . . . ." JA 565. In fact, the DI did no such thing. DI Wright testified that, prior to the August 2009 Compliance Review, he compiled *charts* based on ARCOS data from sales *between 2007 and June 2009*. JA 990-1013, 1099. DI Wright testified that, by presenting *this data* to Masters, he "hoped that . . . Masters' representatives . . . would realize the potential problems with their distribution trends and/or their customers." JA 1099. DI Wright's "intent of displaying this information . . . was to alert [Masters] to potentially problematic trends." JA 1101-02. The Administrator fails to explain how *data* about distributions to certain customers between 2007 and June 2009 (distributions that were the subject of the 2008 OSC the parties had resolved months earlier) should have alerted Masters to deficiencies in the new compliance program it adopted in August 2009.

The Administrator also claims that a memorandum written by a former Masters employee following the Compliance Review suggests that Masters was aware that its limited use of URs was ineffective. JA 565. But, given DEA's contractual duty to advise Masters in writing of any deficiencies in its new compliance program, Masters' failure to scrap that program in favor of the completely new approach advocated in the memorandum can hardly be deemed unreasonable.

Citing *Dantran, Inc. v. U.S. Dept. of Labor*, 171 F.3d 58 (1st Cir. 1999), the Administrator asserts that the DI's negligence in conducting the Compliance Review cannot form the basis for equitable estoppel because he had no "intent to mislead" Masters. JA 565. In so doing, the Administrator sets the bar too high. This Court recently held that "[e]stoppel generally requires that government agents engage—by commission or omission—in conduct that can be characterized as misrepresentation or concealment, or, at least, behave in ways that have or will cause an egregiously unfair result." *Pierce v. SEC*, 786 F.3d 1027, 1038 (D.C. Cir. 2015) (quoting *Gov't Accountability Office v. Gen. Accounting Office Pers. Appeals Bd.*, 698 F.2d 516, 526 (D.C. Cir. 1983)).

If, in fact, as the Administrator has now concluded, Masters' customers did not have a legitimate need to purchase controlled substances, then DI Wright was obligated to say so in writing. And if, as the Administrator has now concluded, Masters had failed to report numerous suspicious orders placed between April and August 2009, then DI Wright was obligated to say so in writing. And if, in fact, Masters was obligated to review customer URs in ways not required by its written policies, then DI Wright was obligated to say so in writing. But, regardless of whether this Court concludes that DI Wright concealed the true results of the Compliance Review, or that DEA simply decided to disavow its own agent's findings in order to reach a conclusion adverse to Masters, it is undoubtedly true

that ignoring Masters' contractual rights—by commission or omission—causes an egregiously unfair result. As the ALJ aptly stated: "Any other conclusion would render useless [Masters'] right under the MOA to receive notice of any deficiencies that amount to ineffective controls. This is no small right, and [Masters] paid no small consideration for it." JA 493.

To prevent an unjust result, this Court must vacate the Final Order.

CONCLUSION

For all of the reasons set forth above, this Court should vacate the Final Order and remand to the agency for proceedings consistent with this Court's order.

Dated: June 28, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

In accordance with Circuit Rule 32(a) and Rule 32(a)(7) of the Federal Rules of Appellate Procedure, the undersigned certifies that the accompanying brief has been prepared using 14-point Times New Roman typeface, and is double-spaced (except for headings and footnotes).

The undersigned further certifies that the brief is proportionally spaced and contains 13,413 words exclusive of the certificate required by Circuit Rule 28(a)(1), disclosure statement required by Circuit Rule 26.1, table of contents, table of authorities, glossary, signature lines, and certificates of service and compliance. The undersigned used Microsoft Word to compute the count.

Dated: June 28, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on this, the 28th day of June, 2016, a true copy of Petitioner's Final Brief, along with the accompanying Statutory and Regulatory Addendum, was served via electronic filing using the appellate CM/ECF system on the following:

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STATUTORY AND REGULATORY ADDENDUM

TABLE OF CONTENTS

Statutes:

Regulations:

5 U.S.C. § 553

semiannual, or other regular periodic report listed in House Document No. 103-7 (in which the report required by subsec. (j) of this section is listed on page 151), see section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.

TERMINATION OF ADMINISTRATIVE CONFERENCE OF UNITED STATES

For termination of Administrative Conference of United States, see provision of title IV of Pub. L. 104-52, set out as a note preceding section 591 of this title.

DECLARATION OF POLICY AND STATEMENT OF PURPOSE

Pub. L. 94-409, § 2, Sept. 13, 1976, 90 Stat. 1241, provided that: "It is hereby declared to be the policy of the United States that the public is entitled to the fullest practicable information regarding the decisionmaking processes of the Federal Government. It is the purpose of this Act [see Short Title note set out above] to provide the public with such information while protecting the rights of individuals and the ability of the Government to carry out its responsibilities."

§ 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 383.)

HISTORICAL AND REVISION NOTES

Derivation	*U.S. Code*	*Revised Statutes and Statutes at Large*
.....	5 U.S.C. 1003.	June 11, 1946, ch. 324, § 4, 60 Stat. 238.

In subsection (a)(1), the words "or naval" are omitted as included in "military".

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In subsection (c), the words "for oral presentation" are substituted for "to present the same orally in any manner". The words "sections 556 and 557 of this title apply instead of this subsection" are substituted for "the requirements of sections 1006 and 1007 of this title shall apply in place of the provisions of this subsection".

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

CODIFICATION

Section 553 of former Title 5, Executive Departments and Government Officers and Employees, was transferred to section 2245 of Title 7, Agriculture.

EXECUTIVE ORDER NO. 12044

Ex. Ord. No. 12044, Mar. 23, 1978, 43 F.R. 12661, as amended by Ex. Ord. No. 12221, June 27, 1980, 45 F.R. 44249, which related to the improvement of Federal regulations, was revoked by Ex. Ord. No. 12291, Feb. 17, 1981, 46 F.R. 13193, formerly set out as a note under section 601 of this title.

§ 554. Adjudications

(a) This section applies, according to the provisions thereof, in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing, except to the extent that there is involved—

(1) a matter subject to a subsequent trial of the law and the facts de novo in a court;

(2) the selection or tenure of an employee, except a[1] administrative law judge appointed under section 3105 of this title;

(3) proceedings in which decisions rest solely on inspections, tests, or elections;

(4) the conduct of military or foreign affairs functions;

(5) cases in which an agency is acting as an agent for a court; or

(6) the certification of worker representatives.

(b) Persons entitled to notice of an agency hearing shall be timely informed of—

(1) the time, place, and nature of the hearing;

(2) the legal authority and jurisdiction under which the hearing is to be held; and

[1] So in original.

5 U.S.C. § 554

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Except when notice or hearing is required by statute, this subsection does not apply—

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Section 553 of former Title 5, Executive Departments and Government Officers and Employees, was transferred to section 2245 of Title 7, Agriculture.

EXECUTIVE ORDER NO. 12044

Ex. Ord. No. 12044, Mar. 23, 1978, 43 F.R. 12661, as amended by Ex. Ord. No. 12221, June 27, 1980, 45 F.R. 44249, which related to the improvement of Federal regulations, was revoked by Ex. Ord. No. 12291, Feb. 17, 1981, 46 F.R. 13193, formerly set out as a note under section 601 of this title.

§ 554. Adjudications

(a) This section applies, according to the provisions thereof, in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing, except to the extent that there is involved—

(1) a matter subject to a subsequent trial of the law and the facts de novo in a court;

(2) the selection or tenure of an employee, except a[1] administrative law judge appointed under section 3105 of this title;

(3) proceedings in which decisions rest solely on inspections, tests, or elections;

(4) the conduct of military or foreign affairs functions;

(5) cases in which an agency is acting as an agent for a court; or

(6) the certification of worker representatives.

(b) Persons entitled to notice of an agency hearing shall be timely informed of—

(1) the time, place, and nature of the hearing;

(2) the legal authority and jurisdiction under which the hearing is to be held; and

[1] So in original.

(3) the matters of fact and law asserted.

When private persons are the moving parties, other parties to the proceeding shall give prompt notice of issues controverted in fact or law; and in other instances agencies may by rule require responsive pleading. In fixing the time and place for hearings, due regard shall be had for the convenience and necessity of the parties or their representatives.

(c) The agency shall give all interested parties opportunity for—

(1) the submission and consideration of facts, arguments, offers of settlement, or proposals of adjustment when time, the nature of the proceeding, and the public interest permit; and

(2) to the extent that the parties are unable so to determine a controversy by consent, hearing and decision on notice and in accordance with sections 556 and 557 of this title.

(d) The employee who presides at the reception of evidence pursuant to section 556 of this title shall make the recommended decision or initial decision required by section 557 of this title, unless he becomes unavailable to the agency. Except to the extent required for the disposition of ex parte matters as authorized by law, such an employee may not—

(1) consult a person or party on a fact in issue, unless on notice and opportunity for all parties to participate; or

(2) be responsible to or subject to the supervision or direction of an employee or agent engaged in the performance of investigative or prosecuting functions for an agency.

An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review pursuant to section 557 of this title, except as witness or counsel in public proceedings. This subsection does not apply—

(A) in determining applications for initial licenses;

(B) to proceedings involving the validity or application of rates, facilities, or practices of public utilities or carriers; or

(C) to the agency or a member or members of the body comprising the agency.

(e) The agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 384; Pub. L. 95–251, § 2(a)(1), Mar. 27, 1978, 92 Stat. 183.)

HISTORICAL AND REVISION NOTES

Derivation	U.S. Code	Revised Statutes and Statutes at Large
.....	5 U.S.C. 1004.	June 11, 1946, ch. 324, § 5, 60 Stat. 239.

In subsection (a)(2), the word "employee" is substituted for "officer or employee of the United States" in view of the definition of "employee" in section 2105.

In subsection (a)(4), the word "naval" is omitted as included in "military".

In subsection (a)(5), the word "or" is substituted for "and" since the exception is applicable if any one of the factors are involved.

In subsection (a)(6), the word "worker" is substituted for "employee", since the latter is defined in section 2105 as meaning Federal employees.

In subsection (b), the word "When" is substituted for "In instances in which".

In subsection (c)(2), the comma after the word "hearing" is omitted to correct an editorial error.

In subsection (d), the words "The employee" and "such an employee" are substituted in the first two sentences for "The same officers" and "such officers" in view of the definition of "employee" in section 2105. The word "officer" is omitted in the third and fourth sentences as included in "employee" as defined in section 2105. The prohibition in the third and fourth sentences is restated in positive form. In paragraph (C) of the last sentence, the words "in any manner" are omitted as surplusage.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

CODIFICATION

Section 554 of former Title 5, Executive Departments and Government Officers and Employees, was transferred to section 2246 of Title 7, Agriculture.

AMENDMENTS

1978—Subsec. (a)(2). Pub. L. 95-251 substituted "administrative law judge" for "hearing examiner".

§ 555. Ancillary matters

(a) This section applies, according to the provisions thereof, except as otherwise provided by this subchapter.

(b) A person compelled to appear in person before an agency or representative thereof is entitled to be accompanied, represented, and advised by counsel or, if permitted by the agency, by other qualified representative. A party is entitled to appear in person or by or with counsel or other duly qualified representative in an agency proceeding. So far as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding, whether interlocutory, summary, or otherwise, or in connection with an agency function. With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it. This subsection does not grant or deny a person who is not a lawyer the right to appear for or represent others before an agency or in an agency proceeding.

(c) Process, requirement of a report, inspection, or other investigative act or demand may not be issued, made, or enforced except as authorized by law. A person compelled to submit data or evidence is entitled to retain or, on payment of lawfully prescribed costs, procure a copy or transcript thereof, except that in a nonpublic investigatory proceeding the witness may for good cause be limited to inspection of the official transcript of his testimony.

(d) Agency subpenas authorized by law shall be issued to a party on request and, when required by rules of procedure, on a statement or showing of general relevance and reasonable scope of the evidence sought. On contest, the court shall sustain the subpena or similar process or demand to the extent that it is found to be in accordance

5 U.S.C. § 556

with law. In a proceeding for enforcement, the court shall issue an order requiring the appearance of the witness or the production of the evidence or data within a reasonable time under penalty of punishment for contempt in case of contumacious failure to comply.

(e) Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 385.)

HISTORICAL AND REVISION NOTES

Derivation	*U.S. Code*	*Revised Statutes and Statutes at Large*
.....	5 U.S.C. 1006.	June 11, 1946, ch. 324, § 6, 60 Stat. 240.

In subsection (b), the words "is entitled" are substituted for "shall be accorded the right". The word "officers" is omitted as included in "employees" in view of the definition of "employee" in section 2105. The words "With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time" are substituted for "with reasonable dispatch" and "except that due regard shall be had for the convenience and necessity of the parties or their representatives". The prohibition in the last sentence is restated in positive form and the words "This subsection does not" are substituted for "Nothing herein shall be construed either to".

In subsection (c), the words "in any manner or for any purpose" are omitted as surplusage.

In subsection (e), the word "brief" is substituted for "simple". The words "of the grounds for denial" are substituted for "of procedural or other grounds" for clarity.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

CODIFICATION

Section 555 of former Title 5, Executive Departments and Government Officers and Employees, was transferred to section 2247 of Title 7, Agriculture.

§ 556. Hearings; presiding employees; powers and duties; burden of proof; evidence; record as basis of decision

(a) This section applies, according to the provisions thereof, to hearings required by section 553 or 554 of this title to be conducted in accordance with this section.

(b) There shall preside at the taking of evidence—

(1) the agency;

(2) one or more members of the body which comprises the agency; or

(3) one or more administrative law judges appointed under section 3105 of this title.

This subchapter does not supersede the conduct of specified classes of proceedings, in whole or in part, by or before boards or other employees specially provided for by or designated under statute. The functions of presiding employees and of employees participating in decisions in accordance with section 557 of this title shall be conducted in an impartial manner. A presiding or participating employee may at any time disqualify himself. On the filing in good faith of a timely and sufficient affidavit of personal bias or other disqualification of a presiding or participating employee, the agency shall determine the matter as a part of the record and decision in the case.

(c) Subject to published rules of the agency and within its powers, employees presiding at hearings may—

(1) administer oaths and affirmations;

(2) issue subpenas authorized by law;

(3) rule on offers of proof and receive relevant evidence;

(4) take depositions or have depositions taken when the ends of justice would be served;

(5) regulate the course of the hearing;

(6) hold conferences for the settlement or simplification of the issues by consent of the parties or by the use of alternative means of dispute resolution as provided in subchapter IV of this chapter;

(7) inform the parties as to the availability of one or more alternative means of dispute resolution, and encourage use of such methods;

(8) require the attendance at any conference held pursuant to paragraph (6) of at least one representative of each party who has authority to negotiate concerning resolution of issues in controversy;

(9) dispose of procedural requests or similar matters;

(10) make or recommend decisions in accordance with section 557 of this title; and

(11) take other action authorized by agency rule consistent with this subchapter.

(d) Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence. The agency may, to the extent consistent with the interests of justice and the policy of the underlying statutes administered by the agency, consider a violation of section 557(d) of this title sufficient grounds for a decision adverse to a party who has knowingly committed such violation or knowingly caused such violation to occur. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(e) The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision in accordance with section 557 of this title and, on payment of lawfully prescribed costs, shall be made available to the parties.

When an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 386; Pub. L. 94–409, § 4(c), Sept. 13, 1976, 90 Stat. 1247; Pub. L. 95–251, § 2(a)(1), Mar. 27, 1978, 92 Stat. 183; Pub. L. 101–552, § 4(a), Nov. 15, 1990, 104 Stat. 2737.)

HISTORICAL AND REVISION NOTES

Derivation	*U.S. Code*	*Revised Statutes and Statutes at Large*
.....	5 U.S.C. 1006.	June 11, 1946, ch. 324, § 7, 60 Stat. 241.

In subsection (b), the words "hearing examiners" are substituted for "examiners" in paragraph (3) for clarity. The prohibition in the second sentence is restated in positive form and the words "This subchapter does not" are substituted for "but nothing in this chapter shall be deemed to". The words "employee" and "employees" are substituted for "officer" and "officers" in view of the definition of "employee" in section 2105. The sentence "A presiding or participating employee may at any time disqualify himself." is substituted for the words "Any such officer may at any time withdraw if he deems himself disqualified."

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

AMENDMENTS

1990—Subsec. (c)(6). Pub. L. 101–552, § 4(a)(1), inserted before semicolon at end "or by the use of alternative means of dispute resolution as provided in subchapter IV of this chapter".

Subsec. (c)(7) to (11). Pub. L. 101–552, § 4(a)(2), added pars. (7) and (8) and redesignated former pars. (7) and (8) and redesignated former pars. (7) to (9) as (9) to (11), respectively.

1978—Subsec. (b)(3). Pub. L. 95–251 substituted "administrative law judges" for "hearing examiners".

1976—Subsec. (d). Pub. L. 94–409 inserted provisions relating to consideration by agency of a violation under section 557(d) of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–409 effective 180 days after Sept. 13, 1976, see section 6 of Pub. L. 94–409, set out as an Effective Date note under section 552b of this title.

HEARING EXAMINERS EMPLOYED BY DEPARTMENT OF AGRICULTURE

Functions vested by this subchapter in hearing examiners employed by Department of Agriculture not included in functions of officers, agencies, and employees of that Department transferred to Secretary of Agriculture by 1953 Reorg. Plan No. 2, § 1, eff. June 4, 1953, 18 F.R. 3219, 67 Stat. 633, set out in the Appendix to this title.

HEARING EXAMINERS EMPLOYED BY DEPARTMENT OF COMMERCE

Functions vested by this subchapter in hearing examiners employed by Department of Commerce not included in functions of officers, agencies, and employees of that Department transferred to Secretary of Commerce by 1950 Reorg. Plan No. 5, § 1, eff. May 24, 1950, 15 F.R. 3174, 64 Stat. 1263, set out in the Appendix to this title.

HEARING EXAMINERS EMPLOYED BY DEPARTMENT OF THE INTERIOR

Functions vested by this subchapter in hearing examiners employed by Department of the Interior not included in functions of officers, agencies, and employees of that Department transferred to Secretary of the Interior by 1950 Reorg. Plan No. 3, § 1, eff. May 24, 1950, 15 F.R. 3174, 64 Stat. 1262, set out in the Appendix to this title.

HEARING EXAMINERS EMPLOYED BY DEPARTMENT OF JUSTICE

Functions vested by this subchapter in hearing examiners employed by Department of Justice not included in functions of officers, agencies, and employees of that Department transferred to Attorney General by 1950 Reorg. Plan No. 2, § 1, eff. May 24, 1950, 15 F.R. 3173, 64 Stat. 1261, set out in the Appendix to this title.

HEARING EXAMINERS EMPLOYED BY DEPARTMENT OF LABOR

Functions vested by this subchapter in hearing examiners employed by Department of Labor not included in functions of officers, agencies, and employees of that Department transferred to Secretary of Labor by 1950 Reorg. Plan No. 6, § 1, eff. May 24, 1950, 15 F.R. 3174, 64 Stat. 1263, set out in the Appendix to this title.

HEARING EXAMINERS EMPLOYED BY DEPARTMENT OF THE TREASURY

Functions vested by this subchapter in hearing examiners employed by Department of the Treasury not included in functions of officers, agencies, and employees of that Department transferred to Secretary of the Treasury by 1950 Reorg. Plan. No. 26, § 1, eff. July 31, 1950, 15 F.R. 4935, 64 Stat. 1280, set out in the Appendix to this title.

§ 557. Initial decisions; conclusiveness; review by agency; submissions by parties; contents of decisions; record

(a) This section applies, according to the provisions thereof, when a hearing is required to be conducted in accordance with section 556 of this title.

(b) When the agency did not preside at the reception of the evidence, the presiding employee or, in cases not subject to section 554(d) of this title, an employee qualified to preside at hearings pursuant to section 556 of this title, shall initially decide the case unless the agency requires, either in specific cases or by general rule, the entire record to be certified to it for decision. When the presiding employee makes an initial decision, that decision then becomes the decision of the agency without further proceedings unless there is an appeal to, or review on motion of, the agency within time provided by rule. On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule. When the agency makes the decision without having presided at the reception of the evidence, the presiding employee or an employee qualified to preside at hearings pursuant to section 556 of this title shall first recommend a decision, except that in rule making or determining applications for initial licenses—

(1) instead thereof the agency may issue a tentative decision or one of its responsible employees may recommend a decision; or

(2) this procedure may be omitted in a case in which the agency finds on the record that due and timely execution of its functions imperatively and unavoidably so requires.

(c) Before a recommended, initial, or tentative decision, or a decision on agency review of the

5 U.S.C. § 706

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 393.)

HISTORICAL AND REVISION NOTES

Derivation	*U.S. Code*	*Revised Statutes and Statutes at Large*
.....	5 U.S.C. 1009(e).	June 11, 1946, ch. 324, §10(e), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

ABBREVIATION OF RECORD

Pub. L. 85–791, Aug. 28, 1958, 72 Stat. 941, which authorized abbreviation of record on review or enforcement of orders of administrative agencies and review on the original papers, provided, in section 35 thereof, that: "This Act [see Tables for classification] shall not be construed to repeal or modify any provision of the Administrative Procedure Act [see Short Title note set out preceding section 551 of this title]."

CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

§ 801. Congressional review

(a)(1)(A) Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing—

(i) a copy of the rule;

(ii) a concise general statement relating to the rule, including whether it is a major rule; and

(iii) the proposed effective date of the rule.

(B) On the date of the submission of the report under subparagraph (A), the Federal agency promulgating the rule shall submit to the Comptroller General and make available to each House of Congress—

(i) a complete copy of the cost-benefit analysis of the rule, if any;

(ii) the agency's actions relevant to sections 603, 604, 605, 607, and 609;

(iii) the agency's actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995; and

(iv) any other relevant information or requirements under any other Act and any relevant Executive orders.

(C) Upon receipt of a report submitted under subparagraph (A), each House shall provide copies of the report to the chairman and ranking member of each standing committee with jurisdiction under the rules of the House of Representatives or the Senate to report a bill to amend the provision of law under which the rule is issued.

(2)(A) The Comptroller General shall provide a report on each major rule to the committees of jurisdiction in each House of the Congress by the end of 15 calendar days after the submission or publication date as provided in section 802(b)(2). The report of the Comptroller General shall include an assessment of the agency's compliance with procedural steps required by paragraph (1)(B).

(B) Federal agencies shall cooperate with the Comptroller General by providing information relevant to the Comptroller General's report under subparagraph (A).

(3) A major rule relating to a report submitted under paragraph (1) shall take effect on the latest of—

(A) the later of the date occurring 60 days after the date on which—

(i) the Congress receives the report submitted under paragraph (1); or

(ii) the rule is published in the Federal Register, if so published;

(B) if the Congress passes a joint resolution of disapproval described in section 802 relating to the rule, and the President signs a veto of such resolution, the earlier date—

(i) on which either House of Congress votes and fails to override the veto of the President; or

(ii) occurring 30 session days after the date on which the Congress received the veto and objections of the President; or

(C) the date the rule would have otherwise taken effect, if not for this section (unless a joint resolution of disapproval under section 802 is enacted).

(4) Except for a major rule, a rule shall take effect as otherwise provided by law after submission to Congress under paragraph (1).

(5) Notwithstanding paragraph (3), the effective date of a rule shall not be delayed by oper-

21 U.S.C. § 823(b)

substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

"(6) The goal of this Act is to encourage the Attorney General to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner. This will also serve to reduce instances of diversion and introduction of some potentially harmful substances into the environment."

PROVISIONAL REGISTRATION

Pub. L. 91-513, title II, §703, Oct. 27, 1970, 84 Stat. 1283, as amended by Pub. L. 99-514, §2, Oct. 22, 1986, 100 Stat. 2095, provided that:

"(a)(1) Any person who—

"(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302 [this section], and

"(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title] or under section 4722 of the Internal Revenue Code of 1986 [formerly I.R.C. 1954, section 4722 of Title 26],

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 [section 823 of this title] for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

"(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 [section 360 of this title] or under such section 4722 [section 4722 of Title 26] (as the case may be) shall be his registration number for purposes of section 303 of this title [section 823 of this title].

"(b) The provisions of section 304 [section 824 of this title], relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

"(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

"(1) the date on which such person has registered with the Attorney General under section 303 [section 823 of this title] or has had his registration denied under such section, or

"(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first."

§ 823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

21 U.S.C. § 823(e)

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

21 U.S.C. § 824

with "on the date of the enactment of the Drug Addiction Treatment Act of 2000," rather than the editorial translation "on October 17, 2000," to reflect the probable intent of Congress.

Subsec. (g)(2)(J)(i). Pub. L. 107–273, § 2501(2), which directed the substitution of "the date referred to in subparagraph (1)," for "October 17, 2000," was executed by making the substitution for text which in the original read "the date of the enactment of the Drug Addiction Treatment Act of 2000," rather than the editorial translation "October 17, 2000," to reflect the probable intent of Congress.

2000—Subsec. (g). Pub. L. 106–310 designated existing provisions as par. (1), substituted "Except as provided in paragraph (2), practitioners who dispense" for "Practitioners who dispense", redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, of par. (1) and redesignated former subpars. (A) and (B) of former par. (2) as cls. (i) and (ii), respectively, of subpar. (B) of par. (1), and added par. (2).

1993—Subsec. (h). Pub. L. 103–200 added subsec. (h).

1984—Subsec. (f). Pub. L. 98–473 amended subsec. (f) generally, substituting provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled research, and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

1978—Subsec. (f). Pub. L. 95–633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

1974—Subsec. (g). Pub. L. 93–281 added subsec. (g).

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110–425, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–56, § 1(c), Aug. 2, 2005, 119 Stat. 591, provided that: "This section [amending this section] shall take effect on the date of enactment of this Act [Aug. 2, 2005]."

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.

A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(d) Suspension of registration in cases of imminent danger

The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall

continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(e) Suspension and revocation of quotas

The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 826 of this title.

(f) Disposition of controlled substances or list I chemicals

In the event the Attorney General suspends or revokes a registration granted under section 823 of this title, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 881(e) of this title. All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) Seizure or placement under seal of controlled substances or list I chemicals

The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

(Pub. L. 91–513, title II, §304, Oct. 27, 1970, 84 Stat. 1255; Pub. L. 93–281, §4, May 14, 1974, 88 Stat. 125; Pub. L. 98–473, title II, §§304, 512, 513, Oct. 12, 1984, 98 Stat. 2050, 2073; Pub. L. 100–93, §8(j), Aug. 18, 1987, 101 Stat. 695; Pub. L. 103–200, §3(d), Dec. 17, 1993, 107 Stat. 2337; Pub. L. 103–322, title XXXIII, §330024(e), Sept. 13, 1994, 108 Stat. 2151; Pub. L. 106–310, div. B, title XXXV, §3502(b), Oct. 17, 2000, 114 Stat. 1227.)

REFERENCES IN TEXT

This subchapter, referred to in subsec. (a)(1), (2), was in the original "this title", meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Subchapter II of this chapter, referred to in subsec. (a)(1), (2), was in the original "title III", meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

AMENDMENTS

2000—Subsec. (a). Pub. L. 106–310, §3502(b)(1), substituted "section 823(g)(1) of this title" for "section 823(g) of this title" in two places in concluding provisions.

Subsec. (d). Pub. L. 106–310, §3502(b)(2), substituted "section 823(g)(1) of this title" for "section 823(g) of this title".

1994—Subsec. (g). Pub. L. 103–322 inserted "or chemical" after "such substance" in last sentence.

1993—Subsec. (a). Pub. L. 103–200, §3(d)(1), inserted "or a list I chemical" after "controlled substance" in introductory provisions and par. (2) and inserted "or list I chemicals" after "controlled substances" in par. (3).

Subsec. (b). Pub. L. 103–200, §3(d)(2), inserted "or list I chemical" after "controlled substance".

Subsec. (f). Pub. L. 103–200, §3(d)(3), inserted "or list I chemicals" after "controlled substances" wherever appearing.

Subsec. (g). Pub. L. 103–200, §3(d)(4), inserted "or list I chemicals" after "controlled substances" in two places and "or list I chemical" after "controlled substance" wherever appearing.

1987—Subsec. (a)(5). Pub. L. 100–93 added par. (5).

1984—Subsec. (a)(3). Pub. L. 98–473, §512(1), inserted provisions relating to suspension, etc., recommended by competent State authority.

Subsec. (a)(4). Pub. L. 98–473, §512(2), added par. (4).

Subsec. (f). Pub. L. 98–473, §304, inserted provisions relating to vesting of right, title, and interest in the United States.

Subsec. (g). Pub. L. 98–473, §513, added subsec. (g).

1974—Subsec. (a). Pub. L. 93–281, §4(a), provided for revocation or suspension of a registration pursuant to section 823(g) of this title for failure of a registrant to comply with standards referred to in such section 823(g).

Subsec. (d). Pub. L. 93–281, §4(b), substituted "A suspension under this subsection" for "Such suspension" in third sentence.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–322 effective 120 days after Dec. 17, 1993, see section 330024(f) of Pub. L. 103–322, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of Title 42, The Public Health and Welfare.

PROVISIONAL REGISTRATION

Applicability of this section to provisional registrations, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

21 U.S.C. § 877

§ 874. Advisory committees

The Attorney General may from time to time appoint committees to advise him with respect to preventing and controlling the abuse of controlled substances. Members of the committees may be entitled to receive compensation at the rate of $100 for each day (including traveltime) during which they are engaged in the actual performance of duties. While traveling on official business in the performance of duties for the committees, members of the committees shall be allowed expenses of travel, including per diem instead of subsistence, in accordance with subchapter I of chapter 57 of title 5.

(Pub. L. 91–513, title II, §504, Oct. 27, 1970, 84 Stat. 1272.)

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

§ 875. Administrative hearings

(a) Power of Attorney General

In carrying out his functions under this subchapter, the Attorney General may hold hearings, sign and issue subpenas, administer oaths, examine witnesses, and receive evidence at any place in the United States.

(b) Procedures applicable

Except as otherwise provided in this subchapter, notice shall be given and hearings shall be conducted under appropriate procedures of subchapter II of chapter 5 of title 5.

(Pub. L. 91–513, title II, §505, Oct. 27, 1970, 84 Stat. 1272.)

§ 876. Subpenas

(a) Authorization of use by Attorney General

In any investigation relating to his functions under this subchapter with respect to controlled substances, listed chemicals, tableting machines, or encapsulating machines, the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place in any State or in any territory or other place subject to the jurisdiction of the United States at any designated place of hearing; except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place where he was served with a subpena. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

(b) Service

A subpena issued under this section may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered on a true copy thereof by the person serving it shall be proof of service.

(c) Enforcement

In the case of contumacy by or refusal to obey a subpena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpena. The court may issue an order requiring the subpenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

(Pub. L. 91–513, title II, §506, Oct. 27, 1970, 84 Stat. 1272; Pub. L. 100–690, title VI, §6058, Nov. 18, 1988, 102 Stat. 4319.)

AMENDMENTS

1988—Subsec. (a). Pub. L. 100-690 inserted "listed chemicals, tableting machines, or encapsulating machines," after "with respect to controlled substances,".

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100-690, set out as a note under section 802 of this title.

§ 877. Judicial review

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

(Pub. L. 91–513, title II, §507, Oct. 27, 1970, 84 Stat. 1273.)

§ 878. Powers of enforcement personnel

(a) Any officer or employee of the Drug Enforcement Administration or any State, tribal,

21 C.F.R. § 1301.44

involved in the denial, revocation, or suspension of any registration, and the granting of any application for registration to import or to manufacture in bulk a basic class of controlled substance listed in Schedule I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

[62 FR 13956, Mar. 24, 1997]

§ 1301.43 Request for hearing or appearance; waiver.

(a) Any person entitled to a hearing pursuant to §1301.32 or §§1301.34–1301.36 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause (or the date of publication of notice of the application for registration in the FEDERAL REGISTER in the case of §1301.34), file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any person entitled to participate in a hearing pursuant to §1301.34 or §1301.35(b) and desiring to do so shall, within 30 days of the date of publication of notice of the request for a hearing in the FEDERAL REGISTER, file with the Administrator a written notice of intent to participate in such hearing in the form prescribed in §1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to §1301.32 or §§1301.34–1301.36 may, within the period permitted for filing a request for a hearing or a notice of appearance, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding such person's position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to §1301.32 or §§1301.34–1301.36 fails to file a request for a hearing or a notice of appearance, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived the opportunity for a hearing or to participate in the hearing, unless such person shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his/her final order pursuant to §1301.46 without a hearing.

[62 FR 13956, Mar. 24, 1997]

§ 1301.44 Burden of proof.

(a) At any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to section 303(a) of the Act (21 U.S.C. 823(a)) are satisfied. Any other person participating in the hearing pursuant to §1301.35(b) shall have the burden of proving any propositions of fact or law asserted by such person in the hearing.

(b) At any hearing on the granting or denial of an applicant to be registered to conduct a narcotic treatment program or as a compounder, the applicant shall have the burden of proving that the requirements for each registration pursuant to section 303(g) of the Act (21 U.S.C. 823(g)) are satisfied.

(c) At any hearing on the granting or denial of an application to be registered to import or export any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to sections 1008(a) and (d) of the Act (21 U.S.C. 958 (a) and (d)) are satisfied. Any other person participating in the hearing pursuant to §1301.34 shall have the burden of proving any propositions of fact or law asserted by him/her in the hearings.

(d) At any other hearing for the denial of a registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 or section 1008(c) and (d) of the Act (21 U.S.C. 823 or 958(c) and (d)) are not satisfied.

(e) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) or section 1008(d) of the Act (21 U.S.C. 824(a) or 958(d)) are satisfied.

[62 FR 13956, Mar. 24, 1997]

§ 1301.45 Time and place of hearing.

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the FEDERAL REGISTER (unless expedited pursuant to § 1301.36(h)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

[62 FR 13956, Mar. 24, 1997]

§ 1301.46 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his/her order on the granting, denial, revocation, or suspension of registration. In the event that an application for registration to import or to manufacture in bulk a basic class of any controlled substance listed in Schedule I or II is granted, or any application for registration is denied, or any registration is revoked or suspended, the order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his/her order upon each party in the hearing.

[62 FR 13956, Mar. 24, 1997]

MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

§ 1301.51 Modification in registration.

(a) Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address by submitting a written request to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Additionally, such a request may be submitted on-line at *www.DEAdiversion.usdoj.gov.*

(1) The request shall contain:

(i) The registrant's name, address, and registration number as printed on the certificate of registration;

(ii) The substances and/or schedules to be added to the registration or the new name or address; and

(iii) A signature in accordance with § 1301.13(j).

(2) If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, the registrant shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate.

(b) Any manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy registered pursuant to this part, may apply to modify its registration to become authorized as a collector by submitting a written request to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Additionally, such request may be submitted on-line at *www.DEAdiversion.usdoj.gov.*

(1) The request shall contain:

(i) The registrant's name, address, and registration number as printed on the certificate of registration;

(ii) The method(s) of collection the registrant intends to conduct (collection receptacle and/or mail-back program); and

(iii) A signature in accordance with § 1301.13(j).

(2) If a hospital/clinic with an on-site pharmacy or retail pharmacy is applying for a modification in registration to authorize such registrant to be a collector to maintain a collection receptacle at a long-term care facility in accordance with § 1317.80 of this chapter, the request shall also include the name and physical location of each long-term care facility at which the

21 C.F.R. § 1301.71

transferred shall be taken in accordance with §1304.11 of this chapter. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with the Administration unless requested by the Special Agent in Charge. Transfers of any substances listed in Schedule I or II shall require the use of order forms in accordance with part 1305 of this chapter.

(2) On the date of transfer of the controlled substances, all records required to be kept by the registrant-transferor with reference to the controlled substances being transferred, under part 1304 of this chapter, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

(3) In the case of registrants required to make reports pursuant to part 1304 of this chapter, a report marked "Final" will be prepared and submitted by the registrant-transferor showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him, if no further transactions involving controlled substances are consummated by him. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant and the substances transferred to him shall be reported as receipts in his/her initial report.

(f) Any registrant that has been authorized as a collector and desires to discontinue its collection of controlled substances from ultimate users shall notify the Administration of its intent by submitting a written notification to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. Additionally, such notice may be submitted on-line at *www.DEAdiversion.usdoj.gov*. When ceasing collection activities of an authorized mail-back program, the registrant shall provide the Administration with the name, registered address, and registration number of the collector that will receive the remaining mail-back packages in accordance with §1317.70(e)(3) of this chapter.

[62 FR 13957, Mar. 24, 1997, as amended at 74 FR 15623, Apr. 6, 2009; 75 FR 10676, Mar. 9, 2010; 76 FR 61564, Oct. 5, 2011; 79 FR 53561, Sept. 9, 2014]

Security Requirements

§1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§1301.72–1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or non-usable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and

(15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§1301.72–1301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§1301.72–1301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Regulatory Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§1301.72, 1301.73 and 1301.75. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in §§1301.72, 1301.73 and 1301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Administration.

(f) A collector shall not employ, as an agent or employee who has access to or influence over controlled substances acquired by collection, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, ''for cause'' means in lieu of, or as a consequence of, any Federal

or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

[36 FR 18729, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 47 FR 41735, Sept. 22, 1982; 51 FR 5319, Feb. 13, 1986; 68 FR 41228, July 11, 2003; 75 FR 10677, Mar. 9, 2010; 79 FR 53561, Sept. 9, 2014]

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

(a) *Schedules I and II.* Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

(b) *Schedules III, IV and V.* Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be

21 C.F.R. § 1301.74

in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be upon the Special Agent in Charge's written determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V controlled substances.

(c) *Multiple storage areas.* Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) *Accessibility to storage areas.* The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

[36 FR 18730, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1301.72, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

All manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. "Limited access" may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: *Provided*, That he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

[36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 39 FR 37984, Oct. 25, 1974]

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration

or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. The supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term ''customer'' includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being

stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

(m) A reverse distributor shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, "for cause" means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1301.74, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 1301.75 Physical security controls for practitioners.

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) Sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by §1317.80(d).

(d) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

(e) Carfentanil etorphine hydrochloride and diprenorphine shall be